Health Services
LOS ANGELES COUNTY

March 6, 2007

313 N. Figueroa Street, Suite 912
Los Angeles, CA 90012

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To improve health through leadership, service and education.

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The Honorable Board of Supervisors
County of Los Angeles
383 Kenneth Hahn Hall of Administration
500 West Temple Street
Los Angeles, California 90012

Dear Supervisors:

CONTRACT AWARD FROM THE DEPARTMENT OF HEALTH AND HUMAN SERVICES TO SUPPORT HANSEN'S DISEASE OUTPATIENT MEDICAL SERVICES AT LAC+USC MEDICAL CENTER
(1st District) (3 Votes)

IT IS RECOMMENDED THAT YOUR BOARD:

1. Approve and instruct the Director of Health Services, or his designee, to accept the attached Contract Award Number HHSH258200730003C, Exhibit I, from the Department of Health and Human Services (DHHS) for the provision of Outpatient Medical Services to Hansen's Disease (leprosy) patients at LAC+USC Medical Center for a total amount of $1,009,569, for the period effective date of full execution by federal government through December 31, 2009, with an annual net County cost of $260,899.

2. Delegate authority to the Director of Health Services, or his designee, to accept and sign amendments, in an amount not to exceed 25% over the base award for the period effective date of full execution by federal government through December 31, 2009, subject to review and approval by County Counsel, the Chief Administrative Office, and notification of Board offices.

PURPOSE/JUSTIFICATION OF THE RECOMMENDED ACTIONS:

Board approval of the recommended actions will authorize the acceptance of a contract award from DHHS to support the continued provision of Hansen's Disease outpatient medical services at LAC+USC Medical Center for individuals in the Los Angeles Catchment area. The contract is in support of the National Hansen's Disease Programs (NHDP), Bureau of Primary Health Care (BPHC), Health Resources and Services Administration (HRSA), DHHS. This program provides outpatient medical services to Hansen's Disease patients with the central goal of preventing disability through early diagnosis and treatment of Hansen's Disease.

FISCAL IMPACT/FINANCING:

The total contract award is in the amount of $1,009,569 for the period effective date of full execution by federal government through December 31, 2009. The annual program cost is $654,660, funded by $336,523 in NHDP funds, estimated Medi-Cal Revenue of $57,248, and net County cost of $260,889.

The break down of the contract award is as follows:

Base Period:	date of full execution by federal government through September 30, 2007	$ 252,392.00
Option Period One:	October 1, 2007 through September 30, 2008	$ 336,523.00
Option Period Two:	October 1, 2008 through September 30, 2009	$ 336,523.00
Option Period Three:	October 1, 2009 through December 31, 2009	$ 84,131.00
	Total:	$1,009,569.00

Funding is included in the Fiscal Year 2006-07 Final Budget and will be requested in future fiscal years, as needed.

FACTS AND PROVISIONS/LEGAL REQUIREMENTS:

The Department of Health Services has been providing care for patients with Hansen's Disease at LAC+USC Medical Center since July 1973.

Since 1981, the DHHS - BPHC has been providing funding for the Hansen's Disease Outpatient Medical Services program at LAC+USC Medical Center.

Over the years, the Board has approved funding from DHHS to support Hansen's Disease outpatient medical services at LAC+USC Medical Center.

On March 30, 2004, the Board approved an Agreement with DHHS for the period of January 1, 2004 through December 31, 2006.

The LAC+USC Hansen's Disease Clinic is designated as the Regional Hansen's Disease Center for the Los Angeles Catchment Area. The Los Angeles Catchment Area includes Santa Barbara, Ventura, Kern, Orange, Tulare, San Luis Obispo, and San Bernadino counties. The other Regional Centers in California are located in San Diego and San Francisco.

County Counsel has approved the Contract Award (Exhibit I) as to form.

Attachment A provides additional information.

CONTRACTING PROCESS:

Not applicable. Advertisement on the Los Angeles County Online Web Site as a contracting opportunity for the National Hansen's Disease Programs is not appropriate as outpatient Hansen's Disease medical services are provided directly by the Department of Health Services at LAC+USC Medical Center.

IMPACT ON CURRENT SERVICES (OR PROJECTS):

Approval of the recommended actions will ensure the continued availability of vital outpatient medical services to Hansen's Disease patients to prevent disability through early diagnosis and treatment.

When approved, this Department requires three signed copies of the Board's action.

Respectfully submitted,

Bruce A. Chernof, M.D.
Director and Chief Medical Officer

BAC:LB
hansenscd4329.lb

Attachments(2)

c: Chief Administrative Officer
County Counsel
Auditor-Controller

ATTACHMENT A

SUMMARY OF LOS ANGELES COUNTY PLAN

1. TYPE OF SERVICE:

Provision of outpatient medical services to Hansen's Disease patients at LAC+USC Medical Center. The program provides services to approximately 656 patients annually.

2. AGENCY ADDRESS AND CONTACT PERSON:

Department of Health and Human Services
National Hansen's Disease Programs
1770 Physicians Park Drive
Baton Rouge, Louisiana 70816-3222
Attention: Suzanne Shumate, Contracting Officer
Telephone: (225) 756-3787 Fax: (225) 756-3786
Email: sshumate@hrsa.gov

3. TERM:

The term of the contract award is effective date of full execution by federal government through September 30, 2007, with two one-year options and one three-month option for a total of three years through December 31, 2009, subject to the availability of funds.

4. GEOGRAPHIC AREAS SERVED:

The Los Angeles Catchment Area includes Santa Barbara, Ventura, Kern, Orange, Tulare, San Luis Obispo, and San Bernadino counties.

5. FINANCIAL INFORMATION:

The total contract award is in the amount of $1,009,569 for the period effective date of full execution by federal government through December 31, 2009. The annual program cost is $654,660, funded by $336, 523 in NHDP funds, estimated Medi-Cal Revenue of $57,248, and net County cost of $260,889.

The break down is as follows:

Base Period:	date of full execution by federal government through September 30, 2007	$ 252,392
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Option Period Two:	October 1, 2008 through September 30, 2009	$ 336,523
Option Period Three:	October 1, 2009 through December 31, 2009	$ 84,131
	Total	$1,009,569

Funding is included in the Fiscal Year 2006-07 Final Budget and will be requested in future fiscal years, as needed.

6. ACCOUNTABILITY FOR PROGRAM MONITORING AND EVALUATION:

Pete Delgado, Chief Executive Officer, LAC+USC Healthcare Network

7. APPROVALS:

LAC+USC Healthcare Network:	Pete Delgado, Chief Executive Officer
Contracts and Grants Division:	Cara O'Neill, Chief
County Counsel (as to form):	Richard K. Mason, Assistant County Counsel

EXHIBIT I

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

National Hansen's Disease Programs
1770 Physicians Park Drive
Baton Rouge LA 70816-3222

December 13, 2006

Our Reference: Contract HHSH258200730003C, Outpatient Hansen's Disease Medical Services

Los Angeles County +University of Southern California Medical Center
Attn: Mark Wycislak
1200 North State Street
Los Angeles CA 90033

Dear Mr. Wycislak,

Enclosed is a fully executed Contract Number HHSH258200730003C. The initial contract period is January 1, 2007 through September 30, 2007.

You are reminded that changes to the contract are not binding unless authorized in writing by the Contracting Officer executing the changes on behalf of the Government.

Thank you for your interest in the National Hansen's Disease Programs. We look forward to working with you. If you have questions, you may contact me at 225-756-3787.

Sincerely,

Suzanne Shumate

Suzanne Shumate
Contracting Officer

Enclosure

[redacted]

AWARD/CONTRACT	1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 350)	RATING	PAGE OF PAGES 1 18

2. CONTRACT (Proc. Inst. Ident.) NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQUEST/PROJECT NO.
HHSH258200730003C	See Block 20C	07-S258-AC-0005

5. ISSUED BY CODE NHDP	6. ADMINISTERED BY (If other than Item 5) CODE NHDP
National Hansen's Disease Program Contracts and Procurement 1770 Physicians Park Drive Baton Rouge LA 70816	National Hansen's Disease Program Contracts and Procurement 1770 Physicians Park Drive Baton Rouge LA 70816

7. NAME AND ADDRESS OF CONTRACTOR (No., Street, City, Country, State and ZIP Code)	8. DELIVERY [X] FOB ORIGIN [ ] OTHER (See below)
LOS ANGELES COUNTY USC MEDICAL CENTER 1200 N STATE STREET LOS ANGELES CA 90033	9. DISCOUNT FOR PROMPT PAYMENT Net 30
	10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN ▶ ITEM
CODE 956000927A FACILITY CODE	

11. SHIP TO/MARK FOR CODE NHDP/AC	12. PAYMENT WILL BE MADE BY CODE
National Hansen's Disease Program Receiving Ambulatory Care 1770 Physicians Park Drive Baton Rouge LA 70816	National Hansen's Disease Program Financial Management Office 1770 Physicians Park Drive Baton Rouge LA 70816

13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION:	14. ACCOUNTING AND APPROPRIATION DATA
[ ] 10 U.S.C. 2304 (c) ( ) [ ] 41 U.S.C. 253 (c) ( )	See Schedule

15A. ITEM NO	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	Continued				
	15G. TOTAL AMOUNT OF CONTRACT ▶				$1,009,569.00

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CONTRACTING OFFICER WILL COMPLETE ITEM 17 OR 18 AS APPLICABLE

17. [ ] CONTRACTOR'S NEGOTIATED AGREEMENT (*Contractor is required to sign this document and return* _____ *copies to issuing office.*) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (*Attachments are listed herein.*)

18. [x] AWARD (*Contractor is not required to sign this document.*) Your offer on Solicitation Number 06-R258-AC-SS02, including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any condition sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your offer, and (b) this award/contract. No further contractual document is necessary.

19A. NAME AND TITLE OF SIGNER (Type or print)	20A. NAME OF CONTRACTING OFFICER
Margaret Berumen OPD Administrator	Suzanne Shumate
19B. NAME OF CONTRACTOR BY Margaret Berumen (Signature of person authorized to sign)	19C. DATE SIGNED 12-5-06
20B. UNITED STATES OF AMERICA BY Suzanne Shumate (Signature of the Contracting Officer)	20C. DATE SIGNED 12/13/2006

NSN 7540-01-152-8069
PREVIOUS EDITION IS UNUSABLE

STANDARD FORM 26 (Rev. 4-85)
Prescribed by GSA
FAR (48 CFR) 53.214(a)

NAME OF OFFEROR OR CONTRACTOR

LOS ANGELES COUNTY USC MEDICAL CENTER

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Tax ID Number: 95-6000927 DUNS Number: 056454895 FOB: Origin Period of Performance: 01/01/2007 to 12/31/2009				
1	Medical Treatment of Hansen's Disease IAW Statement of Work January 1, 2007 through September 30, 2007 Obligated Amount: $252,392.00 Accounting Info: 7570350 3280075 25.6R				252,392.00
2	Medical Treatment of Hansen's Disease IAW Statement of Work October 1, 2007 through September 30, 2008 Amount: $336,523.00(Option Line Item) 01/01/2008 Accounting Info: To be provided upon exercise of option $0.00 (Subject to Availability of Funds)				0.00
3	Medical Treatment of Hansen's Disease IAW Statement of Work October 1, 2008 through September 30, 2009 Amount: $336,523.00(Option Line Item) 01/01/2009 Accounting Info: To be provided upon exercise of option $0.00 (Subject to Availability of Funds)				0.00
4	Medical Treatment of Hansen's Disease IAW Statement of Work October 1, 2009 through December 31, 2009 Amount: $84,131.00(Option Line Item) 01/01/2009 Accounting Info: To be provided upon exercise of option $0.00 (Subject to Availability of Funds) The obligated amount of award: $252,392.00. The total for this award is shown in box 15G.				0.00

PART I – THE SCHEDULE

SECTION B – SUPPLIES OR SERVICES AND PRICES/COSTS

B.1. PURPOSE

The purpose of this contract is to provide Outpatient Hansen's Disease (HD) medical services in the Los Angeles CA Catchment area. There are 656 patients in the area to be served. This contract is in support of the National Hansen's Disease Programs (NHDP), Bureau of Primary Health Care (BPHC), Health Resources and Services Administration (HRSA), Department of Health and Human Services DHHS. The program is to provide outpatient health care services and support HD outreach in areas with HD patient concentrations and to enable this patient population to access these services. The central goal is to prevent disability through early diagnosis and treatment of HD. The anticipated period of performance is one year with two one-year options, for a total of three years.

B.2. PRICE

The price for services filling the requirements of this contract is a firm fixed price of:

BASE PERIOD January 1, 2007 through September 30, 2007	$252,392.00
OPTION PERIOD ONE October 1, 2007 through September 30, 2008	$336,523.00
OPTION PERIOD TWO October 1, 2008 through September 30, 2009	$336,523.00
OPTION PERIOD THREE October 1, 2009 through December 31, 2009	$84,131.00

In accordance with Section C entitled "DESCRIPTION /SPECIFICATION/WORK STATEMENT" and Section F, entitled "Deliverables or Performance" the contractor is to provide the services contained herein.

B.3. WAGE DETERMINATION

This contract is subject to Wage Determination 1994-2047, Revision Number 28, dated 05/23/2006 which is included in Section J, Attachment A.

SECTION C – DESCRIPTION /SPECIFICATION/WORK STATEMENT

C.1 Work Statement

Independently and not as an agent of the Government, the contractor shall furnish all personnel, material, facilities, services and equipment as needed to perform the Statement of Work set forth in Section J, Attachment B attached hereto and made a part of this document.

C.2. Incorporation of Contractor's Proposal

It is understood and agreed that the Contractor shall, in meeting the requirements of this contract, perform the work in accordance with the Contractor's proposal to the National Hansen's Disease Programs for Outpatient Hansen's Disease Medical Services, dated August 31, 2006, as amended by revised proposal dated November 14, 2006, provided however, that to the extent that any provisions of the articles of this contract are in conflict or inconsistent with any provisions of said proposal, the provisions of the articles of this contract shall be controlling and shall supersede the provisions of said proposal.

SECTION D – PACKAGING AND MARKING

All reports and documentation required as Deliverables in Section F shall be marked as instructed in Section F of the contract.

SECTION E – INSPECTION AND ACCEPTANCE

E.1. INSPECTION AND ACCEPTANCE

The Project Officer, as a duly authorized representative of the Contracting Officer, shall assume the responsibilities for monitoring the Contractor's performance, evaluating the quality of services provided by the Contractor and performing final inspection and acceptance of all deliverables.

E.2. FAR 52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

The contract incorporates one or more clauses by reference with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. In addition, the full text of a clause may be accessed electronically at: http://www.arnet.gov/far/

52.246-4 Inspection of Services – Fixed Price (August 1996)

SECTION F – DELIVERIES OR PERFORMANCE

F.1. PERIOD OF PERFORMANCE

The initial period of performance of this contract shall be for one year, beginning January 1, 2007 through September 30, 2007, with two one-year options and one three-month option for a total of three years.

F.2. REPORTING REQUIREMENTS AND DELIVERABLES

(1) The contractor shall submit the items in quantities and during the time periods indicated in the schedule of deliverables to the following address:

(Project Officer)
National Hansen's Disease Programs
1770 Physicians Park Drive
Baton Rouge LA 70816

(2) The Contractor shall deliver all items labeled per instructions, and in the quantity cited, and at the time indicated or before the time indicated in this Article.

(a) All deliverable reports are to carry at the top of the first page the following information:

Contract number
Deliverable item number
Deliverable item delivery due date
Date of submission

(b) All deliverables items are to be separate physical entities.

(c) All deliverables are subject to the review and approval of the Project Officer.

(3) Schedule Of Deliverables

Deliverable	Quantity	Due Date
Outpatient Treatment	As required	Upon patient presentation in clinic
Hansen's Disease Surveillance Report	As Needed	Upon confirmed HD Diagnosis
Hansen's Disease Treatment Reporting Form	As Needed	With Annual Report
Monthly Report	1	NLT 30 days after month end

Annual Report	1	NLT 30 days after year end

In addition to the number of copies to be submitted as shown above, one copy of the final report shall be mailed directly to:

National Hansen's Disease Programs
Attn: Contracting Office
1770 Physicians Park Drive
Baton Rouge LA 70816

F.3 FAR 52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This contract incorporates one or more clauses by reference with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at: http:\\www.arnet.gov/far/

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CONTRACT CLAUSES

52.242-15 Stop Work Order (AUG 1989)

SECTION G – CONTRACT ADMINISTRATION

G.1 DESIGNATION OF PROJECT OFFICER

The person identified below is hereby designated as the Government's Project Officer for this contract. The responsibility of the Project Officer -or his duly authorized representative- is to ensure that the Government's technical objectives are met. To this end the Project Officer will provide necessary information, direction, coordination, et cetera, within the contractual work description. Issuance of changes which affect the articles, terms or conditions of this contract will be accomplished through the Contracting Officer who is the only party authorized to bind the Government to contract:

Project Officer: Kathleen Leonard
National Hansen's Disease Programs
1770 Physicians Park Drive
Baton Rouge LA 70816
Telephone: 225-756-3759
Email: kleonard@hrsa.gov

The Government may unilaterally change its' designated Project Officer

G.2 EVALUATION OF CONTRACTOR'S PERFORMANCE

Interim and final evaluations of Contractor performance shall be conducted on this contract in accordance with the Office of Federal Procurement Policy (OFPP) Policy Letter 92-5 issued January 11, 1993, FAR Subpart 42.15 and HHSAR 342.7002(c)(2)(iv). Upon contract completion, a final evaluation of the Contractor's performance shall be completed by the Government, see Section J, Attachment B.

G.3 SUBMISSION OF INVOICES/VOUCHERS

(1) The Contractor may submit invoices monthly in the amount of $28,043.58 (rounded). See Attachment C.

(2) The Contractor shall also, submit an original and one (1) copy of invoices to the following address:

Health and Resources Services Administration
National Hansen's Disease Programs
Attn: Financial Management Office
1770 Physicians Park Drive
Baton Rouge LA 70816
Reference Contract Number: HHSH258200730003C

(3) For inquiries regarding receiving, inspection and acceptance, rejections, or technical issues, call your respective Project Officer.

(4) Contractor agrees to include the following information on its invoice:

a. Contractor's name, invoice number and date;
b. Task order/contract number;
c. Description, price and quantity of services/products delivered;
d. Date of service;
e. Tax identification number;
f. Contractor's complete remittance address; and
g. Signature of an authorized official certifying that the invoice is correct and proper for payment.

(5) Payment will be Made by:

National Hansen's Disease Programs
Attn: Financial Management Office
1770 Physicians Park Drive
Baton Rouge LA 70816
Telephone Number: 225-756-3769

G.4 KEY PERSONNEL

Pursuant to the Key Personnel clause (HHSAR 352.270-5) referenced in SECTION I of this contract, the following individual(s) is (are) considered to be essential to the work being performed under this contract:

Name	Title
Thomas H. Rea, M.D.	Physician, Medical Director (Project Director)
Helen Baca-Mora	Nursing Care Specialist

The clause cite above contains a requirement for review and approval by the Contracting Officer of written request for change of Key Personnel reasonably in advance of diverting any of these individuals. Receipt of written request at least thirty (30) days prior to a proposed change is considered reasonable.

The person identified above as Project Director shall direct the necessary work and services toward fulfillment of the contractual requirements.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

H.1 CLEARANCE/PRODUCTION OF INFORMATION PRODUCTS/SERVICES

a. DHHS/Office of the Assistant Secretary for Public Affairs requires clearance for any external publication, audiovisual, exhibit, or public affairs service produced for or by Health Resources and Services Administration (HRSA) through this contract as a deliverable (an external publication is one of which 50 copies or more are to distributed outside HHS). This clearance, which takes approximately four (4) weeks, is obtained by the Project Officer through HRSA's Office of Communications.

b. It is the policy of HHS and HRSA that HHS must be prominently and dominantly identified as the primary publisher/producer, to include use of the HHS logo, on all communication materials, including those produced by Contractors (This requirement may be satisfied by displaying the HHS logo on the back cover of a publication). The HRSA logo must be displayed in a position of prominence second only to HHS as the identifier on all communication materials produced on behalf of HRSA, whether by Agency staff, Contractors, or other entities. Communication materials are any and all documents and presentations intended for audiences outside the Agency, including but not limited to:

* fact sheets, newsletters, brochures, flyers
* press releases, advisories, other media materials, Internet publications
* exhibits, posters
* summaries, monographs, proceedings
* slides, overhead transparencies, posters
* audio and videotapes, films

c. Internal Publications (not more than 50 copies are to be distributed outside HHS) are exempt from this requirement. Where appropriate, the words Division of ..., Office..., Bureau..., etc. shall be included below the HRSA logo. **Only the Agency Administrator may grant an exception to the policy.**

d. Title 44 of the U.S. Code requires that the printing of any publication developed under this contract shall be done by the Government Printing Office. Printing shall be coordinated through the Project Officer.

e. OMB clearance must be obtained if you intend to survey or interview more than nine (9) people outside of HRSA and/or the Department, including grantees.

H.2 PRINTING AND DUPLICATING

a. Title 44 of the U.S. Code requires that the printing of Government documents must be accomplished through the Government Printing Office of its field printing plants, unless otherwise approved by the Congressional Joint Committee on Printing (JCP). Contractors and grantees are not intended to be prime or substantial sources of printing for Government agencies. Contractors may prepare copy, illustrative material (forms, etc.) and/or camera ready documents, provided that the printing is less than 5,000 impressions of a single page or up to 25,000 impressions of multiple pages. Printing shall be

coordinated through the Project Officer.

b. Regarding the use of private funds for printing, the regulation state that when appropriated funds are used to create information for publication, the printing of that information cannot be made available to a private publisher for publication without prior approval of the JCP.

SECTION I - CONTRACT CLAUSES

I.1. FAR 52.252-02 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at: **http://www.arnet.gov/far/**

A. FEDERAL ACQUISITION REGULATIONS (FAR) (48 CFR CHAPTER 1)
CONTRACT CLAUSES

Clause No.	Title and Date
52.202-1	Definitions (JUL 2004)
52.203-3	Gratuities (APR 1984)
52.203-5	Covenant Against Contingent Fees (APR 1984)
52.203-6	Restrictions on Subcontractor Sales to the Government (JUL 1995)
52.203-7	Anti-Kickback Procedures (JUL 1995)
52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (JAN 1997)
52.203-10	Price or Fee Adjustment for Illegal or Improper Activity (JAN 1997)
52.203-12	Limitation on Payments to Influence Certain Federal Transactions (SEP 2005)
52.204-4	Printing/Copying Double-Sided on Recycled Paper (AUG 2000)
52.204-7	Central Contractor Registration (OCT 2003)
52.209-6	Protecting the Governments Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment (JAN 2005)
52.215-2	Audit and Records - Negotiation. (JUN 1999)
52.215-8	Order of Precedence--Uniform Contract Format (OCT 1997)
52.215-10	Price Reduction for Defective Cost or Pricing Data (OCT 1997)
52.215-11	Price Reduction for Defective Cost or Pricing Data – Modifications (OCT 1997)
52.215-12	Subcontractor Cost or Pricing Data (OCT 1997)
52.215-13	Subcontractor Cost or Pricing Data – Modifications (OCT 1997)
52.215-15	Pension Adjustments and Asset Reversions (OCT 2004)
52.215-18	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) Other than Pensions (JUL 2005)
52.215-19	Notification of Ownership Changes (OCT 1997)
52.215-21	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data – Modifications (OCT 1997)
52.219-8	Utilization of Small Business Concerns (MAY 2004)
52.219-9	Small Business Subcontracting Plan (JUN 2003) (IF APPLICABLE- Required if total offer - base year plus option years - is over $500,000)
52.222-3	Convict Labor (JUN 2003)
52.222-21	Prohibition of Segregated Facilities (FEB 1999)

52.222-26	Equal Opportunity (APR 2002)
52.222-35	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era and Other Eligible Veterans (DEC 2001)
52.222-36	Affirmative Action for Workers with Disabilities (JUN 1998)
52.222-37	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era and Other Eligible Veterans (DEC 2001)
52.222-41	Service Contract Act of 1965, as amended (JUL 2005)
52.222-42	Statement of Equivalent Rates for Federal Hires (MAY 1989)
52.222-43	Fair Labor Standards Act and Service Contract Act – Price Adjustment (Multiple Year and Option Contracts) (MAY 1989)
52.223-6	Drug-Free Workplace (MAY 2001)
52.223-14	Toxic Chemical Release Reporting (AUG 2003)
52.224-1	Privacy Act Notification (APR 1984)
52.224-2	Privacy Act (APR 1984)
52.225-13	Restrictions on Certain Foreign Purchases (FEB 2006)
52.227-1	Authorization and Consent (JUL 1995)
52.227-2	Notice and Assistance Regarding Patent and Copyright Infringement (AUG 1996)
52.227-14	Rights in Data - General (JUN 1987)
52.229-3	Federal, State and Local Taxes (APR 2003)
52.230-2	Cost Accounting Standards (APR 1998)
52.230-3	Disclosure and Consistency of Cost Accounting Practices (APR 1998)
52.232-1	Payments (APR 1984)
52.232-8	Discounts for Prompt Payment (FEB 2002)
52.232-9	Limitation on Withholding of Payments (APR 1984)
52.232-11	Extras (APR 1984)
52.232-17	Interest (JUN 1996)
52.232-23	Assignment of Claims (JAN 1986)
52.232-25	Prompt Payment (OCT 2003)
52.232-33	Payment by Electronic Funds Transfer –Central Contractor Registration (OCT 2003)
52.233-1	Disputes (JUL 2002)
52.233-3	Protest After Award (AUG 1996)
52.242-13	Bankruptcy (JUL 1995)
52.243-1	Changes – Fixed Price (AUG 1997) Alternate I (APR 1984)
52.244-5	Competition in Subcontracting (DEC 1996)
52.244-6	Subcontracts For Commercial Items and Commercial Components (FEB 2006)
52.246-25	Limitation of Liability--Services (FEB 1997)
52.249-2	Termination for Convenience of the Government (Fixed Price) (MAY 2004)
52.249-8	Default (Fixed Price Supplies and Services) (APR 1984)
52.253-01	Computer Generated Forms (JAN 1991)

[redacted]

B. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CONTRACT CLAUSES

HHSAR Clause No.	Title and Date
352.202-01	Definitions (JAN 2001)
352.224-70	Confidentiality of Information (APR 1984)
352.232-09	Withholding of Contract Payments (APR 1984)
352.242-71	Final Decisions on Audit Findings (APR 1984)
352.270-01	Accessibility of Meetings, Conferences, and Seminars to Persons with Disabilities (JAN 2001)
352.270-4	Pricing of Adjustments (JAN 2001)
352.270-5	Key Personnel (APR 1984)
352.270-06	Publication and Publicity (JUL 1991)
352.270-07	Paperwork Reduction Act (JAN 2001)

I.2 FAR 52.217-8 OPTION TO EXTEND SERVICES (NOV 1999)

The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor by the expiration date of the contract.

I.3. 52.217-9 OPTION TO EXTEND THE TERM OF THE CONTRACT (MAR 2000)

(a) The Government may extend the term of this contract by written notice to the Contractor within 5 days of the option period, provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 60 days before the contract expires. The preliminary notice does not commit the Government to an extension.
(b) If the Government exercises this option, the extended contract shall be considered to include this option clause.

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 36 months.

I.4. 52.204-7 CENTRAL CONTRACTOR REGISTRATION (OCT 2003)

(a) Definitions. As used in this clause-

"Central Contractor Registration (CCR) database" means the primary Government repository for Contractor information required for the conduct of business with the Government.

"Data Universal Numbering System (DUNS) number" means the 9-digit number assigned by Dun and Bradstreet, Inc. (D&B) to identify unique business entities.

"Data Universal Numbering System +4 (DUNS+4) number" means the DUNS number assigned by D&B plus a 4-character suffix that may be assigned by a business concern. (D&B has no affiliation with this 4-character suffix.) This 4-character suffix may be assigned at the discretion of the business concern to establish additional CCR records for identifying alternative Electronic Funds Transfer (EFT) accounts (see the FAR at Subpart 32.11) for the same parent concern.

"Registered in the CCR database" means that-

(1) The Contractor has entered all mandatory information, including the DUNS number or the DUNS+4 number, into the CCR database; and
(2) The Government has validated all mandatory data fields and has marked the record "Active".

(b)(1) By submission of an offer, the offeror acknowledges the requirement that a prospective awardee shall be registered in the CCR database prior to award, during performance, and through final payment of any contract, basic agreement, basic ordering agreement, or blanket purchasing agreement resulting from this solicitation.
(2) The offeror shall enter, in the block with its name and address on the cover page of its offer, the annotation "DUNS" or "DUNS +4" followed by the DUNS or DUNS +4 number that identifies the offeror's name and address exactly as stated in the offer. The DUNS number will be used by the Contracting Officer to verify that the offeror is registered in the CCR database.

(c) If the offeror does not have a DUNS number, it should contact Dun and Bradstreet directly to obtain one.
(1) An offeror may obtain a DUNS number-
(i) If located within the United States, by calling Dun and Bradstreet at 1-866-705-5711 or via the Internet at http://www.dnb.com; or
(ii) If located outside the United States, by contacting the local Dun and Bradstreet office.
(2) The offeror should be prepared to provide the following information:
(i) Company legal business.
(ii) Tradestyle, doing business, or other name by which your entity is commonly recognized.
(iii) Company Physical Street Address, City, State, and Zip Code.
(iv) Company Mailing Address, City, State and Zip Code (if separate from physical).
(v) Company Telephone Number.

(vi) Date the company was started.
(vii) Number of employees at your location.
(viii) Chief executive officer/key manager.
(ix) Line of business (industry).
(x) Company Headquarters name and address (reporting relationship within your entity).

(d) If the Offeror does not become registered in the CCR database in the time prescribed by the Contracting Officer, the Contracting Officer will proceed to award to the next otherwise successful registered Offeror.

(e) Processing time, which normally takes 48 hours, should be taken into consideration when registering. Offerors who are not registered should consider applying for registration immediately upon receipt of this solicitation.

(f) The Contractor is responsible for the accuracy and completeness of the data within the CCR database, and for any liability resulting from the Government's reliance on inaccurate or incomplete data. To remain registered in the CCR database after the initial registration, the Contractor is required to review and update on an annual basis from the date of initial registration or subsequent updates its information in the CCR database to ensure it is current, accurate and complete. Updating information in the CCR does not alter the terms and conditions of this contract and is not a substitute for a properly executed contractual document.

(g) (1) (i) If a Contractor has legally changed its business name, "doing business as" name, or division name (whichever is shown on the contract), or has transferred the assets used in performing the contract, but has not completed the necessary requirements regarding novation and change-of-name agreements in Subpart 42.12, the Contractor shall provide the responsible Contracting Officer a minimum of one business day's written notification of its intention to (A) change the name in the CCR database; (B) comply with the requirements of Subpart 42.12 of the FAR; and (C) agree in writing to the timeline and procedures specified by the responsible Contracting Officer. The Contractor must provide with the notification sufficient documentation to support the legally changed name.

(ii) If the Contractor fails to comply with the requirements of paragraph (g)(1)(i) of this clause, or fails to perform the agreement at paragraph (g)(1)(i)(C) of this clause, and, in the absence of a properly executed novation or change-of-name agreement, the CCR information that shows the Contractor to be other than the Contractor indicated in the contract will be considered to be incorrect information within the meaning of the "Suspension of Payment" paragraph of the electronic funds transfer (EFT) clause of this contract.

(2) The Contractor shall not change the name or address for EFT payments or manual payments, as appropriate, in the CCR record to reflect an assignee for the purpose of assignment of claims (see FAR Subpart 32.8, Assignment of Claims). Assignees shall be separately registered in the CCR database. Information provided to the Contractor's CCR record that indicates payments, including those made by EFT, to an ultimate recipient other than that Contractor will be considered to be incorrect information within the meaning of the "Suspension of payment" paragraph of the EFT clause of this contract.

(h) Offerors and Contractors may obtain information on registration and annual confirmation

requirements via the internet at http://www.ccr.gov or by calling 1-888-227-2423, or 269-961-5757.

PART III – LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J – LIST OF ATTACHMENTS

Attachment A	Los Angeles Wage Determination No.: 1994-2047, Revision 28, 5/23/2006
Attachment B	Statement of Work
Attachment C	Contractor Past Performance Evaluation
Attachment D	Billing Instructions

REGISTER OF WAGE DETERMINATIONS UNDER THE SERVICE CONTRACT ACT
By direction of the Secretary of Labor

William W.Gross
Director

Division of Wage Determinations

U.S. DEPARTMENT OF LABOR
EMPLOYMENT STANDARDS ADMINISTRATION
WAGE AND HOUR DIVISION
WASHINGTON, D.C. 20210

Wage Determination No.: 1994-2047
Revision No.: 27
Date of Last Revision: 05/23/2005

State: California

Area: California Counties of Los Angeles, Orange

OCCUPATION NOTES:

Heating, Air Conditioning and Refrigeration: Wage rates and fringe benefits can be found on Wage Determinations 1986-0879.

Laundry: Wage rates and fringe benefits can be found on Wage Determination 1977-1297.

Fringe Benefits Required Follow the Occupational Listing

OCCUPATION CODE - TITLE	MINIMUM WAGE RATE
01000 - Administrative Support and Clerical Occupations	
01011 - Accounting Clerk I	12 .10
01012 - Accounting Clerk II	13 .35
01013 - Accounting Clerk III	14 .99
01014 - Accounting Clerk IV	16 .80
01030 - Court Reporter	16 .84
01050 - Dispatcher, Motor Vehicle	20 .37
01060 - Document Preparation Clerk	13 .50
01070 - Messenger (Courier)	9 .65
01090 - Duplicating Machine Operator	12 .82
01110 - Film/Tape Librarian	15 .83
01115 - General Clerk I	9 .65
01116 - General Clerk II	10 .69
01117 - General Clerk III	14 .11
01118 - General Clerk IV	15 .15
01120 - Housing Referral Assistant	20 .12
01131 - Key Entry Operator I	11 .28
01132 - Key Entry Operator II	12 .98
01191 - Order Clerk I	14 .12
01192 - Order Clerk II	15 .40
01261 - Personnel Assistant (Employment) I	13 .70

01262 - Personnel Assistant (Employment) II	14 .95
01263 - Personnel Assistant (Employment) III	18 .48
01264 - Personnel Assistant (Employment) IV	22 .26
01270 - Production Control Clerk	19 .06
01290 - Rental Clerk	14 .95
01300 - Scheduler, Maintenance	15 .77
01311 - Secretary I	15 .77
01312 - Secretary II	18 .40
01313 - Secretary III	20 .24
01314 - Secretary IV	22 .59
01315 - Secretary V	25 .48
01320 - Service Order Dispatcher	16 .19
01341 - Stenographer I	13 .56
01342 - Stenographer II	15 .24
01400 - Supply Technician	22 .59
01420 - Survey Worker (Interviewer)	16 .84
01460 - Switchboard Operator-Receptionist	14 .51
01510 - Test Examiner	18 .40
01520 - Test Proctor	18 .40
01531 - Travel Clerk I	12 .45
01532 - Travel Clerk II	13 .50
01533 - Travel Clerk III	14 .48
01611 - Word Processor I	14 .57
01612 - Word Processor II	16 .35
01613 - Word Processor III	18 .29

03000 - Automatic Data Processing Occupations

03010 - Computer Data Librarian	14 .94
03041 - Computer Operator I	14 .94
03042 - Computer Operator II	17 .10
03043 - Computer Operator III	19 .53
03044 - Computer Operator IV	23 .05
03045 - Computer Operator V	25 .52
03071 - Computer Programmer I (1)	19 .20
03072 - Computer Programmer II (1)	24 .07
03073 - Computer Programmer III (1)	27 .62
03074 - Computer Programmer IV (1)	27 .62
03101 - Computer Systems Analyst I (1)	27 .62
03102 - Computer Systems Analyst II (1)	27 .62
03103 - Computer Systems Analyst III (1)	27 .62
03160 - Peripheral Equipment Operator	15 .04

05000 - Automotive Service Occupations

05005 - Automotive Body Repairer, Fiberglass	21 .08
05010 - Automotive Glass Installer	19 .73
05040 - Automotive Worker	19 .73
05070 - Electrician, Automotive	20 .56
05100 - Mobile Equipment Servicer	17 .77
05130 - Motor Equipment Metal Mechanic	21 .08
05160 - Motor Equipment Metal Worker	19 .73
05190 - Motor Vehicle Mechanic	21 .08
05220 - Motor Vehicle Mechanic Helper	16 .45
05250 - Motor Vehicle Upholstery Worker	18 .91
05280 - Motor Vehicle Wrecker	19 .73
05310 - Painter, Automotive	20 .56
05340 - Radiator Repair Specialist	19 .73
05370 - Tire Repairer	15 .47
05400 - Transmission Repair Specialist	21 .08
07000 - Food Preparation and Service Occupations	
(not set) - Food Service Worker	8 .90
07010 - Baker	11 .95
07041 - Cook I	12 .74
07042 - Cook II	14 .12
07070 - Dishwasher	8 .18
07130 - Meat Cutter	13 .15
07250 - Waiter/Waitress	8 .96
09000 - Furniture Maintenance and Repair Occupations	
09010 - Electrostatic Spray Painter	18 .59
09040 - Furniture Handler	12 .42
09070 - Furniture Refinisher	18 .59
09100 - Furniture Refinisher Helper	14 .82
09110 - Furniture Repairer, Minor	17 .04
09130 - Upholsterer	18 .59
11030 - General Services and Support Occupations	
11030 - Cleaner, Vehicles	9 .64
11060 - Elevator Operator	9 .73
11090 - Gardener	14 .20
11121 - House Keeping Aid I	8 .77
11122 - House Keeping Aid II	9 .73
11150 - Janitor	10 .96
11210 - Laborer, Grounds Maintenance	10 .93
11240 - Maid or Houseman	8 .77
11270 - Pest Controller	13 .96

11300 - Refuse Collector	11 .62
11330 - Tractor Operator	13 .18
11360 - Window Cleaner	12 .42

12000 - Health Occupations

12020 - Dental Assistant	14 .92
12040 - Emergency Medical Technician (EMT)/Paramedic/Ambulance Driver	17 .68
12071 - Licensed Practical Nurse I	15 .23
12072 - Licensed Practical Nurse II	17 .06
12073 - Licensed Practical Nurse III	18 .37
12100 - Medical Assistant	13 .47
12130 - Medical Laboratory Technician	17 .18
12160 - Medical Record Clerk	14 .54
12190 - Medical Record Technician	17 .53
12221 - Nursing Assistant I	8 .48
12222 - Nursing Assistant II	9 .54
12223 - Nursing Assistant III	10 .41
12224 - Nursing Assistant IV	11 .69
12250 - Pharmacy Technician	14 .65
12280 - Phlebotomist	12 .86
12311 - Registered Nurse I	25 .96
12312 - Registered Nurse II	31 .74
12313 - Registered Nurse II, Specialist	31 .74
12314 - Registered Nurse III	38 .41
12315 - Registered Nurse III, Anesthetist	38 .41
12316 - Registered Nurse IV	46 .04

13000 - Information and Arts Occupations

13002 - Audiovisual Librarian	20 .59
13011 - Exhibits Specialist I	23 .63
13012 - Exhibits Specialist II	29 .25
13013 - Exhibits Specialist III	34 .77
13041 - Illustrator I	21 .88
13042 - Illustrator II	27 .11
13043 - Illustrator III	33 .62
13047 - Librarian	26 .56
13050 - Library Technician	16 .47
13071 - Photographer I	16 .42
13072 - Photographer II	19 .86
13073 - Photographer III	26 .61
13074 - Photographer IV	30 .51
13075 - Photographer V	36 .92

19000 - Machine Tool Operation and Repair Occupations	
19010 - Machine-Tool Operator (Toolroom)	18 .52
19040 - Tool and Die Maker	23 .95
21000 - Material Handling and Packing Occupations	
21010 - Fuel Distribution System Operator	17 .91
21020 - Material Coordinator	18 .87
21030 - Material Expediter	18 .87
21040 - Material Handling Laborer	13 .02
21050 - Order Filler	12 .38
21071 - Forklift Operator	14 .46
21080 - Production Line Worker (Food Processing)	14 .46
21100 - Shipping/Receiving Clerk	12 .73
21130 - Shipping Packer	12 .73
21140 - Store Worker I	9 .91
21150 - Stock Clerk (Shelf Stocker; Store Worker II)	14 .15
21210 - Tools and Parts Attendant	14 .46
21400 - Warehouse Specialist	14 .46
23000 - Mechanics and Maintenance and Repair Occupations	
23010 - Aircraft Mechanic	22 .33
23040 - Aircraft Mechanic Helper	15 .60
23050 - Aircraft Quality Control Inspector	23 .19
23060 - Aircraft Servicer	17 .94
23070 - Aircraft Worker	18 .72
23100 - Appliance Mechanic	18 .59
23120 - Bicycle Repairer	15 .47
23125 - Cable Splicer	25 .85
23130 - Carpenter, Maintenance	22 .40
23140 - Carpet Layer	17 .96
23160 - Electrician, Maintenance	28 .35
23181 - Electronics Technician, Maintenance I	19 .22
23182 - Electronics Technician, Maintenance II	22 .81
23183 - Electronics Technician, Maintenance III	26 .53
23260 - Fabric Worker	20 .33
23290 - Fire Alarm System Mechanic	20 .30
23310 - Fire Extinguisher Repairer	16 .01
23340 - Fuel Distribution System Mechanic	21 .73
23370 - General Maintenance Worker	17 .78
23430 - Heavy Equipment Mechanic	23 .58
23440 - Heavy Equipment Operator	24 .39
23460 - Instrument Mechanic	24 .29
23470 - Laborer	12 .49

23500 - Locksmith	18 .59
23530 - Machinery Maintenance Mechanic	21 .97
23550 - Machinist, Maintenance	23 .08
23580 - Maintenance Trades Helper	14 .82
23640 - Millwright	21 .56
23700 - Office Appliance Repairer	19 .89
23740 - Painter, Aircraft	18 .59
23760 - Painter, Maintenance	18 .59
23790 - Pipefitter, Maintenance	21 .22
23800 - Plumber, Maintenance	20 .39
23820 - Pneudraulic Systems Mechanic	20 .30
23850 - Rigger	21 .90
23870 - Scale Mechanic	17 .95
23890 - Sheet-Metal Worker, Maintenance	19 .75
23910 - Small Engine Mechanic	17 .78
23930 - Telecommunication Mechanic I	20 .30
23931 - Telecommunication Mechanic II	21 .41
23950 - Telephone Lineman	22 .59
23960 - Welder, Combination, Maintenance	19 .75
23965 - Well Driller	20 .77
23970 - Woodcraft Worker	19 .75
23980 - Woodworker	16 .01
24000 - Personal Needs Occupations	
24570 - Child Care Attendant	11 .36
24580 - Child Care Center Clerk	14 .17
24600 - Chore Aid	10 .13
24630 - Homemaker	16 .98
25000 - Plant and System Operation Occupations	
25010 - Boiler Tender	24 .00
25040 - Sewage Plant Operator	25 .70
25070 - Stationary Engineer	24 .00
25190 - Ventilation Equipment Tender	17 .36
25210 - Water Treatment Plant Operator	25 .70
27000 - Protective Service Occupations	
(not set) - Police Officer	31 .11
27004 - Alarm Monitor	21 .42
27006 - Corrections Officer	23 .19
27010 - Court Security Officer	25 .03
27040 - Detention Officer	23 .19
27070 - Firefighter	27 .63

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27101 - Guard I	9 .61
27102 - Guard II	19 .55
28000 - Stevedoring/Longshoremen Occupations	
28010 - Blocker and Bracer	17 .59
28020 - Hatch Tender	17 .59
28030 - Line Handler	17 .59
28040 - Stevedore I	18 .60
28050 - Stevedore II	19 .75
29000 - Technical Occupations	
21150 - Graphic Artist	23 .34
29010 - Air Traffic Control Specialist, Center (2)	34 .29
29011 - Air Traffic Control Specialist, Station (2)	23 .65
29012 - Air Traffic Control Specialist, Terminal (2)	26 .04
29023 - Archeological Technician I	18 .35
29024 - Archeological Technician II	20 .53
29025 - Archeological Technician III	25 .44
29030 - Cartographic Technician	29 .26
29035 - Computer Based Training (CBT) Specialist/ Instructor	30 .38
29040 - Civil Engineering Technician	26 .21
29061 - Drafter I	17 .40
29062 - Drafter II	20 .27
29063 - Drafter III	23 .58
29064 - Drafter IV	29 .26
29081 - Engineering Technician I	15 .26
29082 - Engineering Technician II	17 .01
29083 - Engineering Technician III	19 .43
29084 - Engineering Technician IV	23 .66
29085 - Engineering Technician V	31 .71
29086 - Engineering Technician VI	38 .38
29090 - Environmental Technician	22 .15
29100 - Flight Simulator/Instructor (Pilot)	36 .76
29160 - Instructor	27 .28
29210 - Laboratory Technician	18 .59
29240 - Mathematical Technician	24 .77
29361 - Paralegal/Legal Assistant I	18 .29
29362 - Paralegal/Legal Assistant II	22 .15
29363 - Paralegal/Legal Assistant III	27 .08
29364 - Paralegal/Legal Assistant IV	32 .78
29390 - Photooptics Technician	23 .33
29480 - Technical Writer	30 .40
29491 - Unexploded Ordnance (UXO) Technician I	21 .79

29492 - Unexploded Ordnance (UXO) Technician II	26 .37
29493 - Unexploded Ordnance (UXO) Technician III	31 .61
29494 - Unexploded (UXO) Safety Escort	21 .79
29495 - Unexploded (UXO) Sweep Personnel	21 .79
29620 - Weather Observer, Senior (3)	20 .99
29621 - Weather Observer, Combined Upper Air and Surface Programs (3)	18 .88
29622 - Weather Observer, Upper Air (3)	18 .88

31000 - Transportation/ Mobile Equipment Operation Occupations

31030 - Bus Driver	16 .22
31260 - Parking and Lot Attendant	8 .49
31290 - Shuttle Bus Driver	12 .32
31300 - Taxi Driver	12 .03
31361 - Truckdriver, Light Truck	12 .32
31362 - Truckdriver, Medium Truck	17 .07
31363 - Truckdriver, Heavy Truck	18 .25
31364 - Truckdriver, Tractor-Trailer	18 .25

99000 - Miscellaneous Occupations

99020 - Animal Caretaker	10 .49
99030 - Cashier	12 .13
99041 - Carnival Equipment Operator	11 .01
99042 - Carnival Equipment Repairer	11 .86
99043 - Carnival Worker	8 .35
99050 - Desk Clerk	12 .65
99095 - Embalmer	19 .16
99300 - Lifeguard	11 .45
99310 - Mortician	23 .46
99350 - Park Attendant (Aide)	14 .38
99400 - Photofinishing Worker (Photo Lab Tech., Darkroom Tech)	14 .25
99500 - Recreation Specialist	16 .23
99510 - Recycling Worker	15 .32
99610 - Sales Clerk	12 .02
99620 - School Crossing Guard (Crosswalk Attendant)	9 .01
99630 - Sport Official	11 .45
99658 - Survey Party Chief (Chief of Party)	30 .93
99659 - Surveying Technician (Instr. Person/Surveyor Asst./Instr.)	23 .28
99660 - Surveying Aide	17 .01
99690 - Swimming Pool Operator	14 .03
99720 - Vending Machine Attendant	11 .75
99730 - Vending Machine Repairer	14 .03
99740 - Vending Machine Repairer Helper	11 .75

ALL OCCUPATIONS LISTED ABOVE RECEIVE THE FOLLOWING BENEFITS:

HEALTH & WELFARE: $2.87 an hour or $114.80 a week or $497.47 a month

VACATION: 2 weeks paid vacation after 1 year of service with a contractor or successor; 3 weeks after 5 years, and 4 weeks after 15 years. Length of service includes the whole span of continuous service with the present contractor or successor, wherever employed, and with the predecessor contractors in the performance of similar work at the same Federal facility. (Reg. 29 CFR 4.173)

HOLIDAYS: A minimum of ten paid holidays per year: New Year's Day, Martin Luther King Jr.'s Birthday, Washington's Birthday, Memorial Day, Independence Day, Labor Day, Columbus Day, Veterans' Day, Thanksgiving Day, and Christmas Day. (A contractor may substitute for any of the named holidays another day off with pay in accordance with a plan communicated to the employees involved.) (See 29 CFR 4.174)

THE OCCUPATIONS WHICH HAVE PARENTHESES AFTER THEM RECEIVE THE FOLLOWING BENEFITS (as numbered):

1) Does not apply to employees employed in a bona fide executive, administrative, or professional capacity as defined and delineated in 29 CFR 541. (See CFR 4.156)

2) APPLICABLE TO AIR TRAFFIC CONTROLLERS ONLY - NIGHT DIFFERENTIAL: An employee is entitled to pay for all work performed between the hours of 6:00 P.M. and 6:00 A.M. at the rate of basic pay plus a night pay differential amounting to 10 percent of the rate of basic pay.

3) WEATHER OBSERVERS - NIGHT PAY & SUNDAY PAY: If you work at night as part of a regular tour of duty, you will earn a night differential and receive an additional 10% of basic pay for any hours worked between 6pm and 6am. If you are a full-time employed (40 hours a week) and Sunday is part of your regularly scheduled workweek, you are paid at your rate of basic pay plus a Sunday premium of 25% of your basic rate for each hour of Sunday work which is not overtime (i.e. occasional work on Sunday outside the normal tour of duty is considered overtime work).

HAZARDOUS PAY DIFFERENTIAL: An 8 percent differential is applicable to employees employed in a position that represents a high degree of hazard when working with or in close proximity to ordinance, explosives, and incendiary materials. This includes work such as screening, blending, dying, mixing, and pressing of sensitive ordance, explosives, and pyrotechnic compositions such as lead azide, black powder and photoflash powder. All dry-house activities involving propellants or explosives. Demilitarization, modification, renovation, demolition, and maintenance operations on sensitive ordnance, explosives and incendiary materials. All operations involving regrading and cleaning of artillery ranges.

A 4 percent differential is applicable to employees employed in a position that represents a low degree of hazard when working with, or in close proximity to ordance, (or employees possibly adjacent to) explosives and incendiary materials which involves potential injury such as laceration of hands, face, or arms of the employee engaged in the operation, irritation of the skin, minor burns and the like; minimal damage to immediate or adjacent work area or equipment being used. All operations involving, unloading, storage, and hauling of ordance, explosive, and incendiary ordnance material other than small arms ammunition. These differentials are only applicable to work that has been specifically designated by the agency for ordance, explosives, and incendiary material differential pay.

** UNIFORM ALLOWANCE **

If employees are required to wear uniforms in the performance of this contract (either by the terms of the Government contract, by the employer, by the state or local law, etc.), the cost of furnishing such uniforms and maintaining (by laundering or dry cleaning) such uniforms is an expense that may not be borne by an employee where such cost reduces the hourly rate below that required by the wage determination. The Department of Labor will accept payment in accordance with the following standards as compliance:

The contractor or subcontractor is required to furnish all employees with an adequate number of uniforms without cost or to reimburse employees for the actual cost of the uniforms. In addition, where uniform cleaning and maintenance is made the responsibility of the employee, all contractors and subcontractors subject to this wage determination shall (in the absence of a

bona fide collective bargaining agreement providing for a different amount, or the furnishing of contrary affirmative proof as to the actual cost), reimburse all employees for such cleaning and maintenance at a rate of $3.35 per week (or $.67 cents per day). However, in those instances where the uniforms furnished are made of "wash and wear" materials, may be routinely washed and dried with other personal garments, and do not require any special treatment such as dry cleaning, daily washing, or commercial laundering in order to meet the cleanliness or appearance standards set by the terms of the Government contract, by the contractor, by law, or by the nature of the work, there is no requirement that employees be reimbursed for uniform maintenance costs.

** NOTES APPLYING TO THIS WAGE DETERMINATION **

Under the policy and guidance contained in All Agency Memorandum No. 159, the Wage and Hour Division does not recognize, for section 4(c) purposes, prospective wage rates and fringe benefit provisions that are effective only upon such contingencies as "approval of Wage and Hour, issuance of a wage determination, incorporation of the wage determination in the contract, adjusting the contract price, etc." (The relevant CBA section) in the collective bargaining agreement between (the parties) contains contingency language that Wage and Hour does not recognize as reflecting "arm's length negotiation" under section 4(c) of the Act and 29 C.F.R. 5.11(a) of the regulations. This wage determination therefore reflects the actual CBA wage rates and fringe benefits paid under the predecessor contract.

Source of Occupational Title and Descriptions:

The duties of employees under job titles listed are those described in the "Service Contract Act Directory of Occupations," Fourth Edition, January 1993, as amended by the Third Supplement, dated March 1997, unless otherwise indicated. This publication may be obtained from the Superintendent of Documents, at 202-783-3238, or by writing to the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Copies of specific job descriptions may also be obtained from the appropriate contracting officer.

REQUEST FOR AUTHORIZATION OF ADDITIONAL CLASSIFICATION AND WAGE RATE {Standard Form 1444 (SF 1444)}

Conformance Process:

The contracting officer shall require that any class of service employee which is not listed herein and which is to be employed under the contract (i.e., the work to be performed is not performed by any classification listed in the wage determination), be classified by the contractor so as to provide a reasonable relationship (i.e., appropriate level of skill comparison) between such unlisted classifications and the classifications listed in the wage determination. Such conformed classes of employees shall be paid the monetary wages and furnished the fringe benefits as are determined. Such conforming process shall be initiated by the contractor prior to the performance of contract work by such unlisted class(es) of employees. The conformed classification, wage rate, and/or fringe benefits shall be retroactive to the commencement date of the contract. {See Section 4.6 (C)(vi)} When multiple wage determinations are included in a contract, a separate SF 1444 should be prepared for each wage determination to which a class(es) is to be conformed.

The process for preparing a conformance request is as follows:

1) When preparing the bid, the contractor identifies the need for a conformed occupation(s) and computes a proposed rate(s).

2) After contract award, the contractor prepares a written report listing in order proposed classification title(s), a Federal grade equivalency (FGE) for each proposed classification(s), job description(s), and rationale for proposed wage rate(s), including information regarding the agreement or disagreement of the authorized representative of the employees involved, or where there is no authorized representative, the employees themselves. This report should be submitted to the contracting officer no later than 30 days after such unlisted class(es) of employees performs any contract work.

3) The contracting officer reviews the proposed action and promptly submits a report of the action, together with the agency's recommendations and pertinent information including the position of the contractor and the employees, to the Wage and Hour Division, Employment Standards Administration, U.S. Department of Labor, for review. (See section 4.6(b)(2) of Regulations 29 CFR Part 4).

4) Within 30 days of receipt, the Wage and Hour Division approves, modifies, or disapproves the action via transmittal to the agency contracting officer, or notifies the contracting officer that additional time will be required to process the request.

5) The contracting officer transmits the Wage and Hour decision to the contractor.

6) The contractor informs the affected employees.

Information required by the Regulations must be submitted on SF 1444 or bond paper.

When preparing a conformance request, the "Service Contract Act Directory of Occupations" (the Directory) should be used to compare job definitions to insure that duties requested are not performed by a classification already listed in the wage determination. Remember, it is not the job title, but the required tasks that determine whether a class is included in an established wage determination. Conformances may not be used to artificially split, combine, or subdivide classifications listed in the wage determination.

ATTACHMENT B STATEMENT OF WORK

A. General Description

The purpose of this contract is to provide Hansen's Disease (HD) outpatient treatment, case management, and follow-up of the HD patients and screening of contacts. Also, provide information and in-service education about HD to healthcare providers in the community, and to serve as HD consultant and resource in the community in the geographic area identified in Section B of the contract. The contractor shall provide all personnel, material, adequate and accessible facilities, services, and equipment required to meet the requirements of this contract.

The number of patients in this area is identified in Section B of the contract. On the basis of experience, it is estimated that these patients will require 4 outpatient visits annually during the period of this contract.

B. Background Information

The legislative authority for the National Hansen's Disease Programs is Public Law 99-117, Section 2.(a.), Section 320, and is guided by DHHS regulations. The Ambulatory Care Program was initiated in 1981 as a consequence of the closing of the U.S.P.H.S. hospitals. Historically, persons with HD were provided care by those facilities in the U.S. In order to continue the mandate of the legislative authority, a Contract Care Program was developed to provide these services in communities where the majority of people with HD lived. Those geographic areas are reflected by the location of the current Outpatient HD Clinics.

Hansen's disease in the United States occurs primarily in California, Louisiana, New York, Puerto Rico, and Texas, and among Asian and Hispanic populations in these areas.

C. Technical Requirements

1. Multidisciplinary Team

The multidisciplinary team that will provide services through the HD program in this contract are considered to be essential to the work being performed. The Director, ACP, must be notified of changes in key personnel, and CVs submitted on any of these who are replaced.

Project Director:
Primary Physician:
HD Clinic RN:

It is estimated that a routine, uncomplicated patient visit for HD services can be completed in 20 minutes, and visit frequency for the monitoring of chemotherapy is an average of four times a year. New cases may require 40 minutes to an hour

for assessment. About 150 – 200 new cases are diagnosed each year in the United States. It is estimated that 20% of the patient population may have complications such as ulcers, reaction, eye, hand, or foot problems which require more time during a clinic visit.

Providers shall be licensed to practice, certified in their specialty, culturally competent, experienced in caring for the targeted population, and have appropriate consultative backup. This team shall include:

a. Physician (part-time)
b. Nurse (part-time)
c. ENT (as needed)
d. Occupational Therapist (as needed)
e. Physical Therapist (as needed)
f. Orthopedist (as needed)
g. Orthotist (as needed)
h. Podiatrist (as needed)
i. Ophthalmologist (as needed)

2. The contractor shall be responsible for providing outpatient care as described herein to those persons designated as eligible for treatment. The contractor shall be responsible for validating the patient's eligibility before rendering services. Patients are considered eligible under the following circumstances:

a. HD Patient – Any individual in the continental United States and Territory of Puerto Rico who has been diagnosed as having HD is automatically eligible for care under this contract.
b. HD contact – Any person who has lived in the same household with a new HD patient in the three year period prior to the diagnosis and the beginning of treatment, shall be examined. If the index case has Paucibacillary disease, only an initial contact exam is necessary. For index cases who have Multibacillary disease, it is recommended that their contacts have annual examinations for at least 5 years.

c. HD Suspect – Individuals suspected of having HD may be referred to the contractor by other physicians or health care agencies. These individuals will be provided with services required to rule out the disease. (See Required Services.)

When the eligibility status of an individual patient is unclear, the contractor shall obtain guidance and approval from the Project Officer.

3. **Required Services**

The purpose of the Outpatient Hansen's Disease Program is to provide outpatient medical and diagnostic services for HD and its related conditions.

Services to be provided through this contract, according to the following protocol include:

(a) Patient Assessment:

Evaluation of a patient with suspected or confirmed HD shall include a complete history and physical exam as outlined in the Standards Of Care (see Appendix) for HD in the United States.

Hansen's disease affects the skin, peripheral nerves, anterior part of the eyes, and the nasal area. In the advanced form of the disease (Lepromatous leprosy), it can cause gynecomastia and testicular atrophy in males. A complete physical assessment of the patient is necessary. Diagnostic criteria include the presence of anesthetic lesions with M. leprae in skin smears or biopsies, and sometimes, peripheral nerve enlargement.

Eyes: Examine the eye for inflammation, complete closure, and pupil size. In patients with borderline lepromatous or lepromatous disease, an ophthalmological exam shall be done to rule out eye involvement in this disease.

Skin: Hypo- or hyper-pigmented flat or raised lesions, are most commonly found on the face, extremities, buttocks, or thighs. Absence of sweating, hair loss, or changes in texture of the skin may also be present.

Nerves: Peripheral nerves may be enlarged or tender. The ulnar, median, radial cutaneous, posterior tibial, and peroneal nerves are most commonly affected. In patients with anesthesia of the hands or feet, ulcerations, muscle atrophy, or deformity may be present. A common complaint is pain in the extremities and a burning sensation in the soles of the feet.

(b) Diagnostic Studies:

Punch Biopsy: A 4 mm punch biopsy or larger is needed for diagnosis.
Skin Smears: These may be done on initial exam on all patients, and annually on all Multibacillary patients for a total of 5 years. (See Standards of Care.)

[redacted]

(c) Laboratory Monitoring:

Drug	Laboratory Test	Frequency
All drugs	CBC with platelet Count, UA, Chem 20, G6PD	Baseline
Dapsone	G6PD, CBC	Baseline Every six months
Rifampin	CBC with platelet Count, Chem 20	Every 3 months
Clofazimine	No requirements	

-Other Tests

PCR Assay (Polymerase Chain Reaction)
In a non-endemic population, the sensitivity and specificity of PCR assay recommend its use primarily to identify M.Leprae when acid-fast organisms are discernible but atypical clinical or histopathologic features are obscuring the diagnosis. The Assay is not highly informative when acid-fast bacilli are not detectable by light microscopy. (Am J Clin Pathol 1998; 109:642-646)

To further determine whether this Assay would be clinically appropriate, contact Dr. David Scollard, Chief of Pathology, Research Department, NHDP, at 225-578-9841.

(d) Treatment

The Standards of Care in the Appendix provide guidelines which shall be used to determine treatment of HD under this contract.

The Treatment Protocol for Hansen's Disease in the U.S. is multi- drug therapy which includes the drugs Dapsone, Rifampin and Clofazimine.

(e) Consultant Services

Due to the multi-faceted aspects of this disease, patients shall be referred to the following ancillary medical services for treatment of complications as necessary:

(1) ENT
(2) Occupational Therapy

(3) Ophthalmology
(4) Orthopedics
(5) Orthotics
(6) Physical Therapy
(7) Podiatry

Clinical consultations with staff at the National Hansen's Disease Programs (NHDP) are available by calling 1-800-642-2477.

(f) Rehabilitation Services

Disability prevention is promoted by the visual inspection of the eyes, hands, and feet of the patient at each encounter. If the hand or foot requires further evaluation, a hand or foot screen and palpation of the nerves shall be done. (See appendix, Standards of Care for procedures.)

For patients scheduled to receive care at the NHDP in Baton Rouge, the Ambulatory Care therapist coordinates care with the NHDP therapists. Preoperative casting, wound care and postoperative rehabilitation provided by the therapist in the Ambulatory Care setting decreases the length of stay required for care at the NHDP.

(1) **Eye** – Ophthalmological services may be needed for patients with eye problems that may be caused by HD, such as incomplete eyelid closure, loss of corneal sensation, or infiltration of the eye with HD bacilli.

(2) **Occupational Therapy** – Services required for the performance of this contract include performing hand screens and reporting changes in sensory and motor function to the physician, teaching prevention of disability, providing wound care, fabricating splints and casts, recommending assistive devices, rehabilitation tendon transfers and other orthopedic procedures, and in collaboration with the medical staff, identifying candidates for reconstructive surgery.

- **Hand Screens** – These are a means of assessing the HD patient's risk category for hand problems, and for developing a care plan for their prevention and treatment.

  The sensory testing device used with the Hand Screen is a set of five (5) calibrated nylon filaments mounted on a small rod, which measure levels of cutaneous touch and pressure on a scale of 2.83 to 6.65. The normal threshold level is 2.83.

(3) **Physical Therapy** services include the following:

- **Foot Screens** – The Foot Screen has been proven to accurately identify patients who are at risk of developing deformities as a result of insensitivity, and also provides a baseline for determing the extent of foot disabilities.

  The sensory testing device used with the Foot Screen is a nylon filament mounted on a holder is designed to deliver a 10 gram force when properly applied. Our research has shown that a patient can feel the 10 gram filament in the selected sites will not develop ulcers.

(4) **Frequency of Performance**:

(a) Hand and foot screens shall be done for new patients at the time of diagnosis.

(b) Annually until stable for 3 years. During reactions or neuritis, screens shall be done more frequently as clinically indicated.

(c) After 3 years, annually until skin smear is negative.

The hand and foot filament sets for the Ambulatory Care Clinics may be obtained by calling 1-800-642-2477.

(5) **Hand And Foot Rehabilitation**

An efficient and comprehensive rehabilitation program in the management of insensitive limbs shall incorporate physical therapy, occupational therapy, pedorthics, and patient education. Rehabilitation goals aimed at minimizing loss of function, ulceration, amputation, and ultimate disability, can be satisfactorily achieved utilizing the following interdisciplinary rehab practices: hand and foot care, exercise, wound care, foot care, splinting, casting, and electromyography.

(g) **Hours of Operation** - The contractor shall provide hours of operation adequate to support the HD patient population in the area. These services must be provided in a culturally appropriate and competent manner.

(h) **Inpatient Care** – Medical staff in Baton Rouge may authorize an inpatient admission to the NHDP at Ochsner Medical Center, Baton Rouge, Louisiana, on a case-by-case basis.

(i) **Leprosy Surveillance Form** – All newly diagnosed cases of HD shall be documented on a Hansen's Disease Surveillance Form. This form can be obtained from the NHDP website (www.bphc.hrsa.gov/nhdp) as well as in the Standards of Care Appendix.

(j) **HD Contact Surveillance** – Any person who has lived in the same household with a new HD patient in the three year period prior to the diagnosis and the beginning of treatment, shall be examined. If the index case has Tuberculoid disease, only an initial contact exam is necessary. For index cases who have Borderline Lepromatous or Lepromatous HD, it is recommended that their contacts have annual examinations for at least 5 years.

(k) **Patient and Professional Education** – Appropriate treatment of stigmatizing disease like HD involves concerns about deformity, disability, isolation, job loss, and being a source of infection to their families. Awareness of these patient concerns will more likely ensure patient compliance with treatment.

In order to achieve its objective, which is the prevention of deformity and disability, the patient assessment, hand and foot screens, HD monitors, and contact exam shall be used to educate patients and family about HD.

The majority of healthcare providers in the U.S. are not aware of HD in the population. Providers serving populations from endemic areas shall be targeted for educational services on HD in order to increase their index of suspicion for HD.

Educational materials are available from the NHDP (See "Resources" in the Standards of Care in the Appendix).

(l) **Patient Transportation** – Reimbursement for travel to the HD Clinics may be provided through this contract for indigent patients when it is deemed necessary by the HD clinic staff.

(m) **Self-Evaluation** – Contractors shall include a self-evaluation plan that involves monitoring the implementation of the program and compliance with the Standards of Care. These program monitoring/self-evaluation activities shall not require the services of outside evaluators or consultants.

(n) **Subcontractors** - The contractor shall provide all necessary health services related to HD either directly or through subcontractors. The contractor is responsible for payments to subcontractors.

(o) **Medical Records** – The contractor shall have adequate systems in place to ensure the confidentiality of patient medical records.

(p) **Third Party Reimbursement** – The contractor shall screen all patients for any type of medical coverage to obtain third party reimbursement.

D. Reporting Requirements (See Appendix, Standards of Care for Forms)

1. A Hansen's Disease Surveillance Form shall be completed on all newly-diagnosed patients as soon as the diagnosis is confirmed.

2. The contractor shall submit, semi-annually, an electronic report on diskette or CD generated with the use of Microsoft Access or compatible database with the following information:

a. Name of all patients, birth date, social security number, and address
b. Number of clinic visits, if any, for each patient during the reporting period
c. HD medications each patient is receiving with start and stop date
d. Type and number of consultant visits (OT, PT, etc.) per patient during the reporting period, including referrals to NHDP
e. Hard copy of all hand and foot screens performed during the reporting period

3. Annual Report:

a. Report of all deceased patients, including birth date, social security number, date and cause of death, if known.
b. A brief description of the annual independent audit. If deficiencies were identified, note them and how they were corrected and addressed.

4. Other reports and information to be determined by the Project Officer as part of an ongoing evaluation program to determine the effectiveness of the care provided under this contract.

E. Reference Material

The Standards of Care in the appendix provide guidelines for treatment of Hansen's disease in the U.S.

Copies of the protocols, reporting forms, and consent forms are available from the National Hansen's Disease Program.

Questions regarding treatment regimens shall be directed to the Clinical Branch at NHDP. More information is available about HD and our services on the NHDP website, www.bphc.hrsa.gov/nhdp.

APPENDIX – STANDARDS OF CARE

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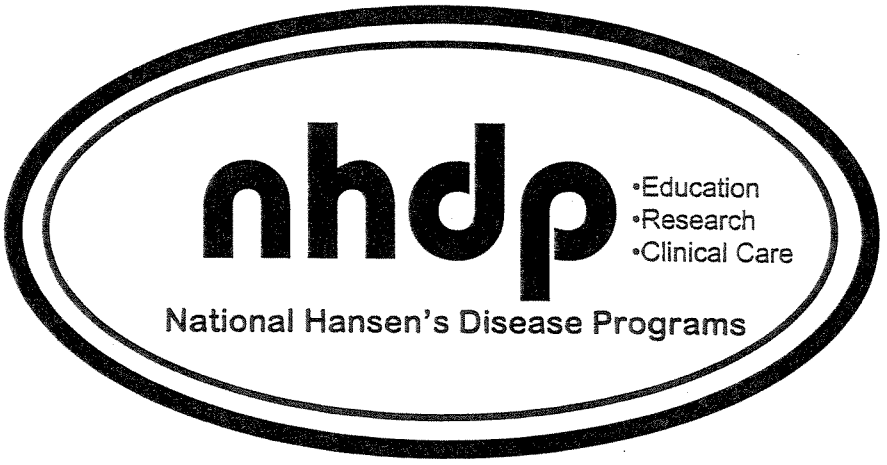

HANSEN'S DISEASE
STANDARDS OF CARE
in the
UNITED STATES

National Hansen's Disease Programs
1770 Physicians Park Drive
Baton Rouge, Louisiana 70816
Phone: 1-800-642-2477
Website: bphc.hrsa.gov/nhdp

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With a very special acknowledgement to all the Staff of the Outpatient Hansen's Disease Clinics who have contributed their expertise since 1981 to the knowledge base of Hansen's disease care in this country. Their dedication and skills have most certainly given hope and lessened some of the burden of those affected by this disease.

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INTRODUCTION

MISSION

The National Hansen's Disease Program (NHDP) is an activity in the Department of Health and Human Services (DHHS), and the Bureau of Primary Health Care (BPHC). It is authorized by Public Law 99-117, Section 2. (a), Section 320 and is guided by DHHS regulations. The NHDP is charged with the responsibility of providing Hansen's disease (HD) treatment for individuals with this disease through the NHDP, in Baton Rouge, Louisiana, and through its Ambulatory Care Program.

ELIGIBILITY

Any individual living in the United States and Puerto Rico may receive outpatient medical care for the diagnosis and treatment of HD and its complications. Contacts of these patients are also eligible for services as described by NHDP policy.

OBJECTIVE

The goal of the Ambulatory Care Program is to prevent deformity and disability from HD through early diagnosis and treatment. The purpose of this Manual is to serve as a resource for the Standards of Care in the treatment of HD in the United States (U.S.).

HISTORY

The NHDP in the United States has a 100-year history of caring for people diagnosed with this disease. It began in 1896 at an abandoned plantation home in Carville, Louisiana, with the Daughters of Charity of St.Vincent de Paul from the state of Maryland as volunteers. They provided basic services to a small group of patients from the city of New Orleans, and continued through the development of the federally-funded Gillis W. Long Hansen's Disease Center in Carville. The Center became the only inpatient facility for HD in the country.

In the early 40's, the use of sulfone therapy by Dr. Guy Faget resulted in the development of dapsone as a bactericidal agent against Mycobacterium leprae, the mycobacteria that causes the disease. This led to the greatest change in patient care, for patients could now be discharged from "Carville" and new patients treated as outpatients. The year 1960 saw the initiation of rehabilitative procedures introduced by Dr. Paul Brand, an orthopedic surgeon, which have effectively decreased the frequency of amputation of the lower extremities. In the 1970's, rifampin was added to the multi-drug regimen that is the recommended therapy in the U.S.

NATIONAL HANSEN'S DISEASE PROGRAMS

In 1981, the Federal Government initiated the Ambulatory Care Program, which provides HD medical care throughout Outpatient Clinics in various facilities located where most of the patients live in the U.S. and Puerto Rico. Services provided by these Clinics include diagnosis and treatment of HD and related conditions, laboratory monitoring, consultant services, and patient and community education.

In 1999 the Federal Government transferred the facility at Carville to the State of Louisiana. Ambulatory residential patients were permitted to stay at Carville if they wished, with outpatient medical services provided there. Long-term, residential patients requiring continuous nursing services were relocated to the Hansen's Unit at Ochsner Medical Center in Baton Rouge, Louisiana. Patients referred by the Outpatient HD Clinics or by private physicians are also admitted to Ochsner Medical Center.

PRIVATE PHYSICIAN PROGRAM

HD medications can be provided to patients living in an area not served by an HD clinic. Their private physician can order the HD medications (dapsone, rifampin, clofazimine) from the NHDP at no charge to the patient. Consultant and biopsy processing services are also provided to the physician, and a patient may be referred to the NHDP in Baton Rouge upon consultation with the medical staff. Transportation assistance to Ochsner Medical Center may be available if necessary.

EPIDEMIOLOGY

Hansen's disease cases reported to the National Hansen's Disease Registry have totaled approximately 12,000 cases to date. Of these cases, roughly 75% are foreign born in endemic countries with 25% of the cases considered to be endemic. While California, Texas, Hawaii, Louisiana, and New York collectively account for about 70% of the total reported cases, the states of Texas, Louisiana, and Hawaii represent 75% of the reported endemic cases. Although the number of cases reported annually is affected considerably by immigration patterns, the average number of annual cases reported over the past decade is 130.5.

Hansen's disease occurs in all age groups with a U.S. median age at diagnosis of 35.0 years. The disease exhibits a gender bias with twice as many male cases as female. A race/ethnicity breakdown shows that three fourths of the reported cases are represented by the Asian/Pacific Islander and White Hispanic groups, but fully 50% of the endemic cases are classified as White, Not Hispanic.

BACTERIOLOGY

HD is caused by Mycobacterium leprae, a slow-growing, acid-fast bacillus. The incubation period for HD may be two-five years, although it can be as long as 15-20 years or more. The disease is probably spread through airborne droplets from the nasal mucosa and upper

airways of a person with untreated disease, or through prolonged skin contact with this person. Armadillos may also carry the disease. The communicability of HD is very low, however, and about 95% of the world's population has a natural immunity to this bacillus. A person with HD becomes non-communicable within one week of starting treatment.

MANAGEMENT OF HANSEN'S DISEASE

CLINICAL PRESENTATION

HD affects the skin, peripheral nerves, eyes, and mucous membranes of the upper respiratory tract, especially the nose. Nerve damage caused by the bacillus may result in anesthesia and deformities of the hands and feet and lagophthalmos of the eyes. In lepromatous HD there may be iritis, direct invasion of the anterior part of the eye by the bacilli, and in males, it may cause testicular atrophy and gynecomastia. A complete physical assessment of the patient is necessary.

In most people, resistance develops to infection with M.leprae. The body's defenses kill the invading bacteria, or contain the infection so disease does not develop. In persons with limited or no resistance to the disease, the bacteria grow slowly, eventually leading to the appearance of symptoms. Presence of the bacteria will be demonstrated with skin smears or biopsy.

Hypo- or hyper-pigmented, flat or raised lesions appear which may be insensitive to light touch. These most commonly appear on the buttocks, thighs, trunk, and lateral aspect of the upper and lower extremities. There may be anhidrosis, loss of hair on the skin, excluding the scalp, and changes in skin texture. The earlobes may be swollen and pendulous.

Patients may experience inflammation of the eyes, excessive or decreased tearing, loss of lateral eyebrows, and incomplete closure of the eyelids, and loss of corneal sensation.

Muscle strength of the hands and feet may be affected. There may be dryness, decreased sensation, muscle atrophy, deformity such as clawing of fingers or toes, wounds, and ulcers. Male patients may have painful, swollen testicles or gynecomastia.

Peripheral nerves may be enlarged or tender. The ulnar, median, radial cutaneous, posterior tibial, peroneal, and greater auricular are most commonly affected. Some patients complain of pain in the extremities, and a burning sensation in the soles of the feet. Abnormal nerves will feel sclerosed.

Effects of Hansen's Disease on Peripheral Nerves

Disability and deformity in HD are primarily due to nerve damage. The damage is caused by bacilli in the perineurium, by the influx of inflammatory cells attracted by the intraneural bacilli, by the sheer bulk of bacillary material in both Schwann cells and invading macrophages, and by fibrosis occurring in the inflamed nerve. In addition to sensory loss or

muscle paralysis, other effects of this denervation are anhydrosis and decreased oil production in the skin. This causes the skin to become dry and inelastic, leading to difficulties in healing when trauma occurs. The functionally important nerves most commonly damaged are the facial, ulnar, median, radial, peroneal, and posterior tibial.

Most of the disability and deformity in HD is secondary due to repetitive trauma and infection of insensitive areas. These secondary effects of nerve damage are preventable. Persons with normal sensation rely on the sense of pain to warn them of possible trauma and are able to prevent serious injury. Those who have lost sensation have to learn other methods of protecting insensitive areas from injury. The specific psychological effects associated with a significant loss of sensation also need to be considered.

The Peripheral Nerves

- The Facial Nerve - The orbicularis muscle, innervated by the facial nerve, is affected in about 15% of persons with HD. Damage to this nerve results in lagophthalmos, exposing the cornea to possible damage, especially during sleep. Loss of corneal sensation will compound the problem because the blink reflex may be compromised.

- Ulnar, Median, and Radial Nerves - Most commonly, the ulnar nerve is involved at the elbow and the wrist, and the median nerve is damaged just proximal to the wrist and in the carpal tunnel. Early signs are dryness of the hands, callus formation, and signs of trauma due to insensitivity, such as burns. The result of severe nerve damage will be atrophy of the intrinsic muscles of the hand, including the hypothenar and thenar areas. There may be clawing of the digits and weakness of pinch (ulnar) loss of opposition of the thumb (median), and wrist drop (radial).

- Peroneal and Posterior Tibial Nerve - Damage to the peroneal nerve causes anesthesia in the lateral aspect of the lower extremities and dorsum of the feet. The motor deficit is in the peroneal muscles and dorsiflexors of the foot; the earliest sign is difficulty in dorsiflexion or eversion of the foot against pressure. The result of a full motor deficit in this area is foot drop. Damage to the posterior tibial nerve will result in anesthesia of the plantar surface of the foot, and claw toes. Observe for a high-stepping, inverted gait, callus formation on the toes and plantar surface, and erythematous or warm pressure areas on the foot.

- Sensory Testing of Hands and Feet - Sensory testing of hands and feet with nylon filament should be done at the time of diagnosis and periodically during treatment to detect evidence of nerve damage at the earliest possible stages. This is an important part of disability prevention. Early detection of problems makes it possible to take steps which can prevent further nerve damage.

Surgery

Most patients with HD do not require any surgery but there are occasional situations in which the following surgical procedures can assist in therapy or rehabilitation:

- Incision and Drainage-Draining of abscesses, debriding ulcers; removal of necrotic bone from infected lesions.

- Tendon transfer procedure-For drop foot or mobile claw hand

- Surgical release of nerves-Release of the osteoligamental tunnels where nerves are liable to constrictions (ulnar at the elbow, median nerve at the wrist, posterior tibial behind the medial malleolus)

- Arthrodesis of claw toes and procedures for stabilization of Charcot foot.

Silent Neuritis

There are some patients who have no signs of reaction or nerve pain, but continue to have progressive sensory or motor loss in hands or feet. Such patients need to be assessed to determine that they are receiving appropriate chemotherapy since noncompliance with drug intake could contribute to this problem. However, there are still some patients who are taking their medications regularly and still have deteriorating nerve function. The cause of this deterioration is not known, but is known that some of these patients will have improvement if they receive steroid treatment. If the loss of function has been 3 months or less, they should be given a course of steroids in the dose range for reactions. If the loss has been present for longer than 3 months the chance of recovery is diminished. Therefore, it is important to monitor all patients under treatment for any changes in nerve function and treat accordingly.

HD and Pregnancy

A female with HD who is pregnant is rare in the U.S., but a few cases occur each year. The majority of these pregnancies are uneventful as far as HD is concerned, but there are a number of potential problems and risks that should be considered when advising female HD patients of childbearing age, and when managing patients who are already pregnant and have HD.

All female patients of childbearing age should be advised to avoid pregnancy during early stages of the disease, at least until MDT has been completed and preferably until the disease is completely inactive. The postponement of pregnancy is especially important for patients who have evidence of reaction or neuritis since these problems will be exacerbated during pregnancy and the postpartum period. There may also be a very small risk of transmission of the disease from mother to infant in those cases where the pregnancy occurs before treatment or early in the course of treatment.

There are alterations in the immune response during all pregnancies, causing a depression of the cell-mediated immune system. This immune suppression during pregnancy and its recovery in the postpartum period appears to play a role in the clinical manifestations of HD in women. It is common for the first symptoms of HD in young women to occur during

pregnancy or the postpartum period. An increased risk of relapse during pregnancy has also been reported.

ENL is more common during pregnancy when the CMI is depressed, while reversal reaction is more common during the postpartum period when the CMI is recovering.

The risk of reactions or neuritis during pregnancy will vary considerably with the type of disease and the amount of treatment a patient has received prior to the pregnancy. If a reaction occurs during a pregnancy, it should be managed as in non-pregnant patients with the use of prednisone sufficient to control the reaction and prevent nerve damage. Thalidomide cannot be used.

For patients who are or become pregnant during the early stages of the disease, chemotherapy should generally continue during pregnancy with some modification of the regimens in some cases. We avoid the use of rifampin during pregnancy if possible. Dapsone can be continued throughout the pregnancy.

Patients who have had HD some time in the past, who have been adequately treated, and whose disease is now completely inactive, can be expected to have essentially normal pregnancies. There is no risk of the mother transmitting the disease to infants in such cases.

HD and Children

HD in children is uncommon in the U.S., but does occur and is usually indeterminate or tuberculoid type disease. It is usually a benign disease with very few deformities reported. Management of the disease is generally the same as for adults except for the adjustment of drug dosages to be determined by the physician. Transmission of HD to children should not occur after the adult patient starts on treatment that includes rifampin. Preventive treatment is not generally recommended for child contacts. The presence of new cases in children usually indicates that HD is still being transmitted in the general population.

Testicular HD

Direct invasion of the testicles probably occurs in most cases of Borderline and Lepromatous disease, although testicular dysfunction is most common in Lepromatous disease. The testicles are a cool part of the body and are preferentially affected. If HD is not treated early, there is progressive destruction of testicular tissue and eventually testicular atrophy with sterility and a decrease in testosterone production.

Gynecomastia usually develops relatively late and is an indication of advanced disease. Acute orchitis may develop during ENL and may be an indication for prednisone therapy. Testicular atrophy is usually permanent. After testicular function is destroyed, the only treatment is testosterone replacement. This does not restore fertility but is helpful in restoring sexual potency. Injectables are the preferred route for replacement therapy. Oral androgens are not recommended for long-term therapy because of potential liver toxicity.

DIAGNOSTIC CRITERIA

The presence of anesthetic skin lesions with acid-fast bacilli in skin smears or biopsies are diagnostic of HD. Sometimes enlarged peripheral nerves may also be present.

SCHEDULE OF SERVICES

I. New Patient
- A. Patient Interview
- B. HD Monitors
- C. Medical Assessment
- D. Biopsy
- E. Skin Smears (optional)
- F. Baseline laboratory studies
- G. Hand and Foot Screens
- H. HD Surveillance Form
- I. HD Patient Education

II. Follow-Up Visit
- A. Patient Interview
- B. HD Monitors
- C. Medical Assessment
- D. Laboratory monitoring every three months or as necessary
- E. Skin Smears annually (optional)
- F. Hand and Foot Screens every six months or as necessary
- G. Patient Education every clinic visit

PATIENT ASSESSMENT

I. Patient Interview
- A. Family History of HD
- B. Presenting Symptoms
  1. No pain reported with injuries such as cuts or burns
  2. Recurrent nosebleeds
  3. Chronic nasal congestion
  4. Burning sensation on soles of feet or hands
  5. Painful / tender peripheral nerves
- C. Psychological considerations
  1. Stigma/myths
  2. Sharing diagnosis-family, friends, boss, colleagues
  3. Common concerns-cause, treatment, contagiousness, sexual relations, deformities
- D. Teaching Plan
  1. Address patient concerns
  2. Treatment, length, medication side-effects
  3. Prognosis, prevention of deformity, reaction

4. Refer to support group (e.g., IDEA)

E. Standards for Performance
   1. First interview should include all elements above with initiation of D., Teaching Plan
   2. Follow-up visits should include B., C., and continuation of D.

II. Physical Assessment

A. Skin-It is important to perform a complete examination of the skin in good light. Hypopigmented of hyperpigmented flat or raised lesions may be found on the face, trunk, extremities, buttocks, or thighs. Absence of sweating, hair loss, or changes in texture of the skin may also be present. Ask male patients about pain or swelling of the testicles and examine for erythematous nodules.

B. Eyes-Examine the eyes for inflammation, incomplete closure of the eyelids, and pupil size. In patients with borderline lepromatous disease, an ophthalmological exam should be done to rule out eye involvement in patients with borderline lepromatous and lepromatous disease.

C. Nerves-A peripheral nerve assessment should be done to determine if nerves are enlarged or tender (See Appendix).The ulnar, median, radial cutaneous, posterior tibial, and peroneal nerves are commonly affected. In patients with anesthesia of the hands or feet, ulcerations, muscle atrophy, or deformity may be present. A common complaint is pain in the extremities and a burning sensation in the soles of the feet.

D. Hands and Feet-Hands and feet should be examined for dryness, diminished sensation, muscle weakness or muscle atrophy, wounds, and ulcers.

E. HD Monitors-The purpose of this exam is to perform a visual inspection and assessment of motor function of the eyes, hands, and feet of a patient with HD. It is an excellent venue for teaching patients about the prevention of complications. (See Appendix for procedure)

F. Performance Standard
   1. Loss of sensation associated with a lesion requires a biopsy be performed to diagnose HD
   2. HD Monitors should be performed at each patient visit
   3. Patients with eye problems should be referred to an ophthalmologist.
   4. Patients with hand or foot problems should have hand and foot screens done, and referred as necessary

LABORATORY MONITORING

I. Schedule

Drug	Laboratory Test	Frequency
All drugs	CBC with platelet Count, UA, Chem 20, G6PD	Baseline
Dapsone	G6PD, CBC	Baseline Every six months
Rifampin	CBC with platelet count, Chem 20	Every three months
Clofazimine	No requirements	
Thalidomide	CBC with differential	Every three months

II. Other tests

A. UA should be done annually with these studies for all patients.

B. PCR Assay (Polymerase Chain Reaction)
In a non-endemic population, the sensitivity and specificity of PCR assay recommend its use primarily to identify M.leprae when acid-fast organisms are discernible but atypical clinical or histopathologic features are obscuring the diagnosis. The Assay is not highly informative when acid-fast bacilli are not detectable by light microscopy. (Am J Clin Pathol 1998; 109:642-646) To further determine whether this Assay would be clinically appropriate, contact Dr. David Scollard, Chief of Pathology, Research Department, NHDP, at 225-578-9841.

C. Performance Standard

1. Baseline laboratory studies are performed on all patients before initiation of chemotherapy
2. Follow-up laboratory monitoring is done quarterly on patients receiving MDT which includes rifampin
3. Other laboratory monitoring is performed according to indicated schedule for medication

TREATMENT OF HD IN THE U.S.

I. Clinical Spectrum of HD

The clinical features of HD cover a wide range, from a single hypopigmented skin macule to very generalized disease. Wide differences are seen in the pathological features, immunological status, treatment required, and types of complications that develop. For treatment purposes, the NHDP uses the WHO two-group classification, into which the Ridley-Jopling five-group classification is incorporated.

II. Treatment

Treatment of HD involves more than simply prescribing medication. Many patients fear they will become severely disabled and will spread the disease to their families. They also fear they will suffer socially if others find out. Good health education at the time of diagnosis and during the course of treatment will make it more likely that the patient will have a better outcome. Thus, an important part of the management of HD is providing accurate information to patients and families regarding the expected course and prognosis of the disease.

A. Paucibacillary (PB)-Dapsone 100mg daily plus rifampin 600 mg. daily for one year and then stop treatment
   1. Indeterminate (I) HD is the earliest stage of disease, and consists of one or two vague hypopigmented macules, slightly dry in texture, with anhidrosis, and generally, no M.leprae in the lesion. Over half of these cases resolve without treatment, others progress eventually into one of the other forms of HD.
   2. Tuberculoid (TT) is limited disease with few, well-defined hypopigmented skin lesions which have marked sensory loss. Loss of hair in the lesion is common and there is often central healing. Without treatment, lesions may enlarge slowly, or self-heal. M.leprae are few or hard to find, but peripheral nerve involvement common, leading to severe disabilities if nerve damage occurs.

B. Multibacillary (MB)-Dapsone 100mg daily plus rifampin 600 mg daily plus clofazimine 50 mg daily for two years, and then stop treatment.
   1. Borderline (BT, BB, BL) disease has features of both the tuberculoid and lepromatous types of HD. Skin lesions occur in small and large sizes and may be hypo- or hyper-pigmented. These lesions may or may not be anesthetic.
   2. Lepromatous (LL) type disease is characterized by lesions which are numerous, small, and symmetrically distributed. They may be hypo- or hyper-pigmented. The skin, nerves, bones, eyes, and nasal area are most often affected; however, all organs may become involved. There may be elongated ear

lobes with partial or complete loss of the eyebrows. There may be anhidrosis of some parts of the body.

C. Common Side-effects of HD medications

1. Dapsone
   a. Contraindications-prior allergy to dapsone G6PD deficiency, breast-feeding
   b. Side effects-hemolysis
2. Rifampin
   a. Contraindications-prior allergy to rifampin
   b. Side effects-abnormal liver function, thrombocytopenia, drug interactions with oral contraceptives and anticoagulants, reddish discoloration of urine, stools, saliva, tears, and sweat
3. Clofazimine
   a. Contraindications-none indicated
   b. Side effects-discoloration of skin, diarrhea, abdominal pain, and less commonly, bowel obstruction

On November 1, 2004, Novartis Pharmaceuticals Corporation ceased distribution of lamprene (clofazimine) in the U.S. through its usual distribution channels. It will only be available now through Investigational New Drug (IND) protocol. To receive clofazimine for treatment of HD, you must be enrolled as an investigator under the IND held by NHDP. To enroll, contact Renee Painter at:

National Hansen's Disease Programs
1770 Physicians Park Drive
Baton Rouge, LA 70816
rpainter@hrsa.gov
Phone: (225) 756-3773, Fax (225) 756-3806

Although the drug has been used in children and pregnant women for years, these groups are specifically excluded due to regulations covering any investigational research use in these groups. Any minor less than 18 years old is excluded even with parental consent. Women of childbearing age need a negative pregnancy test before beginning clofazimine and must discontinue their medicine if they are pregnant. For questions regarding this process, please call Barbara Stryjewska, MD, Principal Investigator/Sponsor, at 1-800-642-2477.

4. In the event of intolerance or drug toxicity to the usual drugs, the NHDP may be contacted for recommendations regarding alternative regimens.

D. Performance Standard
   1. Biopsy is done to determine type of HD for proper treatment to be initiated
   2. Baseline laboratory studies are performed before initiating treatment
   3. Drug allergy is ruled out through patient's medical history
   4. Patients presenting with complaints of side-effects from HD medications are assessed by nurse and referred to HD clinic physician for treatment
   5. Patient education includes medications, dosages, and side effects of medications, clofazimine consent forms read, explained, and signed as necessary, required visit for laboratory monitoring

E. Follow-Up after Completion of Treatment
   Clinical examinations and biopsies or skin smears
   Should be done at the following intervals:
   1. Paucibacillary (PB)
      a. Every six months for two years
      b. Annually for three years
   2. Multibacillary (MB)
      a. Every six months for two years
      b. Annually for eight years

F. Performance Standard
   1. Follow-up for Paucibacillary disease is done according to schedule in E.1. above
   2. Multibacillary disease is followed up per schedule in E.2. above

REACTIONS IN HD

Although M.leprae is almost non-toxic, some patients develop acute hypersensitivity "reactions" to the organism. These are known as "lepra reactions". Reports of the frequency of reactions indicate that 25% to 50% of all HD patients will have a reaction sometime during the course of the disease. There are no predictors of which patients will develop reaction, other than patients with tuberculoid disease do not have reactive episodes. Reactions are also less frequent in patients taking clofazimine. There are two types of reaction, Reversal Reaction or Type I Reaction, and Erythema Nodosum Leprosum, or ENL, which is Type II Reaction. Most patients with reaction can be treated as outpatients. For guidance on management of reaction, call the NHDP at 1-800-642-2477.

I. Symptoms of Reaction
   A. Neuritis-enlarged or tender peripheral nerves; changes in sensation or strength
   B. Muscle weakness
   C. Tender, painful, erythematous nodules which may ulcerate
   D. Development of new lesions

E. Malaise
F. Fever-low-grade to moderate
G. Red, painful eyes
H. Orchitis in patients with multibacillary disease
I. Edema of hands and feet

II. Treatment of Reactions

Reactions are a major cause of nerve damage, so the focus of management should be on the prevention of nerve damage. Damage to the nerves is caused by the tissue response within the nerves to intraneural M. leprae and is similar to the process seen in the skin. In untreated HD without reaction, nerve damage is more insidious, while in reaction, nerves may be damaged more rapidly. Skin reactions and acute neuritis often occur together. Antibacterial treatment should be continued at full dosage.

Patients with mild reaction may be treated symptomatically. Those with moderate to severe reaction may require steroids, thalidomide, or clofazimine. Patients with severe reaction, especially those with evidence of nerve damage, require treatment with corticosteroids.

A. Treatment with steroids
   1. Contraindications
      a. Inadequately treated infection
      b. Situation where medically supervised stoppage of medication is not possible
      c. Prolonged usage without close medical supervision
   2. Side effects
      a. Weight gain or potassium loss
      b. New infection or exposure to an infectious person
      c. Poor response to some immunizations
      d. Interaction with laboratory or medical procedures such as blood sugar and TB skin tests
      e. Withdrawal effects

B. Thalidomide is very effective in controlling ENL, and is the drug of first choice if not contraindicated. This drug is very teratogenic and causes severe birth defects if taken by women during pregnancy.

In the U.S., Thalidomide is available to the prescribing physician and the dispensing pharmacist by registering with Celgene's System (888-423-5436) for Thalidomide Education and Prescribing Safety (STEPS) program, and the medication will be provided to the HD patient at no cost.

Male patients taking this medication must use prophylactics during sexual intercourse. Pregnancy tests at regular intervals are required for female patients of childbearing age.

1. Contraindications

a. Pregnancy
b. No unauthorized person may take this medication

2. Side effects
   a. Fetal developmental defects
   b. Constipation
   c. Drowsiness
   d. Dizziness

C. Clofazimine can be given in a dose of 300mg daily for four to six weeks, reduced to 200 mg daily for several months, and then reduced to 100mg daily. The addition of clofazimine at these doses will usually make it possible to reduce the dose of steroids required, but not eliminate them entirely. Clofazimine is not quick acting and it may take six weeks or more for the full effect on the reaction to be noted. Patients receiving larger doses of clofazimine will have more severe skin pigmentation and more frequent gastro-intestinal side effects.

When the patient has required no steroids for approximately three months, the dosage of clofazimine can be reduced to 50mg daily. If clofazimine is not required for antibacterial treatment, it can be discontinued when no steroids have been required for an additional three months.

For consultation on the treatment of reaction, call the NHDP at 1-800-642-2477. For more information on reaction, see "Resources".

D. Performance Standard
   1. Medical assessment and treatment should be done on patients with symptoms of reaction in order to prevent permanent nerve injury.
   2. Patient knows symptoms of reaction to report to healthcare provider
   3. Patient knows side-effects of medication prescribed for reaction which must be reported for evaluation
   4. Patients on thalidomide have documented consent forms indicating that procedures and STEPS protocol have been explained and are being followed

CONTACT SURVEILLANCE

In the U.S., a contact is identified as a person living in the same household with a new patient, up to three years, at the time of diagnosis. A contact exam includes:

I. Contact examination
   A. Exam of the entire skin
   B. Nerve function assessment of the peripheral nerves, focusing primarily on the eyes, hands, and feet (See Appendix).

C. The contact exam should also include patient education on the disease, and what symptoms a contact should report to the health care provider.

An individual suspected of having HD may be referred to one of the Outpatient HD Clinics or to the NHDP by physicians or healthcare agencies. These persons will be provided with the services required to rule out the diagnosis of HD, as described above.

II. Follow-Up of Contacts

A. For contacts of a paucibacillary case, no follow-up is necessary, as long as the patient has been educated about the symptoms of HD.

B. In contacts of a multibacillary case, exams should be done annually for five years, including patient education about the disease and its symptoms

C. The NHDP does not recommend chemoprophylaxis with dapsone or any other drug for contacts of patients.

D. Performance Standard

1. Exam of contacts or suspects includes all aspects described under a, "Contact Exam", above.
2. Follow-up exams are done according to the schedule above.
3. Patient education provided to contacts is documented.

CONSULTANT SERVICES

I. Due to the multi-faceted aspects of this disease, patients may need referral to the following ancillary medical services for complications. Not all consultant services will be needed in every case and some will be indicated only rarely. Consultation with NHDP staff is also available by calling 1-800-642-2477.

A. Physical Therapy
B. Occupational Therapy
C. Podiatry
D. Orthotics
E. Orthopedics
F. Ophthalmology
G. ENT

II. Performance Standard

Patients with complications from HD will be referred to consultants as necessary.

REHABILITATION SERVICES

I. Disability prevention is promoted by the visual inspection of the eyes, hands, and feet of the patient at each encounter. Should the hands or feet require further evaluation, a hand or foot screen and palpation of the nerves should be done (See Appendix).

II. Services include:

A. Eye-Ophthalmological services are needed for persons with paucibacillary HD who may have incomplete palpebral closure or loss of corneal sensation. Patients with multibacillary disease may have infiltration of the anterior part of the eye with HD bacilli. Patients with eye complaints should be referred to the ophthalmologist.

B. Occupational and Physical Therapy-These services include hand and foot screens, reporting changes in sensory and motor function to the physician, teaching prevention of disability, providing wound care, fabricating splints and casts, recommending assistive devices, rehabilitation tendon transfers and other orthopedic procedures, and in collaboration with the medical staff, identifying candidates for reconstructive surgery.

C. Preoperative casting, wound care, and post-operative rehabilitation provided by Ambulatory Care Program therapists decreases the length of stay required for those patients referred to the NHDP.

III. Performance Standard

A. Hand and Foot Screens and Peripheral Nerve Exam are performed on all patients according to schedule or as necessary

B. Patients with positive findings receive medical assessment and referral to consultant services as necessary.

PROFESSIONAL AND PATIENT EDUCATION

I. Patient Education

Appropriate treatment of a stigmatizing disease like HD involves more than merely prescribing medications. Many patients fear they will become severely disabled and will infect their families. They also fear social isolation if others become aware of their diagnosis. Awareness of these patient concerns at the time of diagnosis and during the course of treatment will more likely ensure patient compliance with treatment and achieve its objective, which is the prevention of deformity and disability. Printed and audiovisual materials are available from the NHDP.

A. Physical assessment, HD monitors, hand and foot screens all offer opportunities for patients to learn about HD and how it affects them.

B. Incorporate disability prevention into all patient education

II. Professional Education

A. Asian and Hispanic minority populations represent the largest number of patients diagnosed in the U.S. These communities should be included in the community outreach educational programs by the healthcare provider

B. Encourage medical and nursing students to participate in or visit the HD clinic

C. Provide the local medical association with information about HD clinic services for publication in their newsletter; invite local media to include information about HD clinic services and HD as part of community service news

III. Standard of Care
   A. Patient education is documented on all patient encounters, including hand and foot screens.
   B. Education is geared to disability prevention, elimination of deformity, and associated stigma
   C. Program evaluation will reflect professional educational activities such as student rotations, lectures at other healthcare facilities, media involvement in education of community about HD

INPATIENT CARE

Medical staff at the NHDP may authorize an inpatient admission on a case-by-case basis.

RESOURCES

I. Resources available from the NHDP
   A. Consultation on treatment and management guidelines
   B. Medications for HD: dapsone, rifampin, clofazimine
   C. Processing and reading of skin smears
   D. Processing biopsies for histopathology
   E. Hand and foot screen forms
   F. Professional and patient audiovisual and printed educational materials
   G. HD and Foot Seminars for Physicians, Nurses, Occupational Therapists, Physical Therapists, Orthotists, and Podiatrists
   H. NHDP Website-www.bphc.hrsa.gov/nhdp

   Information regarding these services and materials is available from the NHDP, 1770 Physicians Park Drive, Baton Rouge, LA, 70816, Phone 800-642-2477; Fax 225-756-3760

II. Other Resources
   A. American Leprosy Missions
      1 ALM Way
      Greenville, SC 29601
      Phone: 800-543-3131
   B. IDEA (International Association for Integration, Dignity, And Economic Advancement)
      U.S. Headquarters
      P.O. Box 651
      32 Fall Street-Suite A
      Seneca Falls, NY 13148
      Phone: 315-568-5838 Fax: 315-568-5891
      E-mail:alaw@idealeprosydignity.org

HD REPORTING REQUIREMENTS

The following reports must be sent to the NHDP, 1770 Physicians Park Drive, Baton Rouge, LA 70816:

I. A Hansen's Disease Surveillance Form on all newly-diagnosed patients as soon as the diagnosis is confirmed.

II. The contractor shall submit an electronic report semi-annually on a diskette generated with the use of Microsoft Access or compatible database with the invoice containing the following information:

- A. Name of all patients, birth date, social security number, and address
- B. Number of clinic visits for each patient during the reporting period
- C. HD medications each patient is receiving and start date
- D. Type and number of consultant visits (OT, PT, etc.) per patient during the reporting period
- E. Hard copy of all hand and foot screens performed during the reporting period

III. Annual Reports

- A. Report of all deceased patients including birth date, social security number, date and cause of death, if known.

- B. A brief description of annual independent audit. If deficiencies were identified, note them and how they were corrected and addressed.

IV. Other reports and information to be determined by the Project Officer as part of an ongoing evaluation program to determine the effectiveness of the care provided under this contract.

APPENDIX

Hansen's Disease Monitors

The Hansen's disease (HD) monitors are a system of assessment which includes a visual inspection and assessment of motor function of the eyes, hands, and feet of a patient with HD. These procedures can be used to teach patients about prevention of complications.

1. **Visual Inspection**

   a.. Eyes

      1. Examine the eyes for inflammation
      2. Check the pupil size, shape, and reaction to light
      3. Ask the patient to close their eyes and check for incomplete closure

   b. Hands

      1. Inspect the palms and dorsum of the hands for dry skin
      2. Check for muscle atrophy and injuries

   c. Feet

      1. Inspect for dry skin, erythema, calluses, and injuries
      2. Check socks and shoewear for signs of drainage from ulcers or injuries

2. **Motor Function Assessment**

   These assessments should be done with the application of resistance by the examiner, otherwise early signs of weakness may be missed. (See attachment)

3. **Shoewear Assessment for Insensitive Feet**

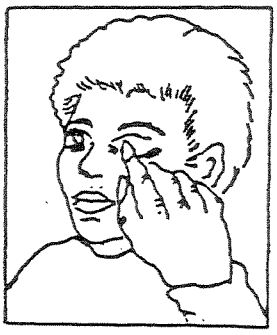
   a. Extra-depth shoes with removable insoles
   b. Rounded or square toe box
   c. Leather upper
   d. A half-inch length beyond longest toe
   e. No seams at the toe
   f. Soft wedge sole

A patient with a positive eye exam should be evaluated by an ophthalmologist; hand and foot problems need follow-up with a hand or foot screen and referred as necessary.

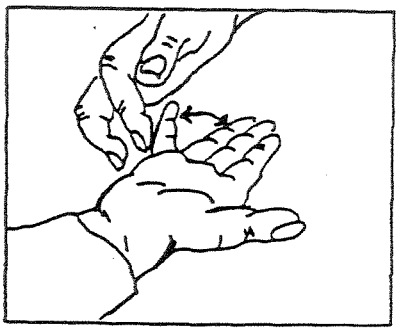
[redacted]

HANSEN'S DISEASE MONITORS

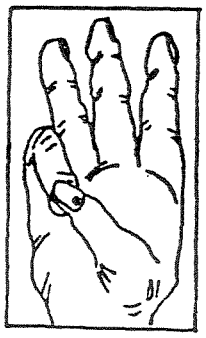
FACIAL NERVE
Have patient close eyes while applying gentle resistance to eyelids.



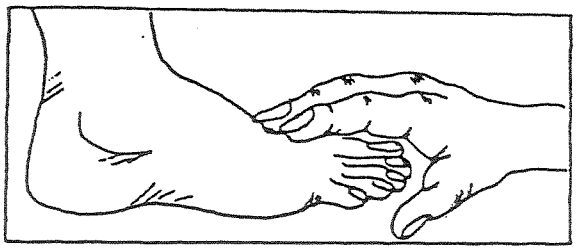
ULNAR NERVE
Have patient abduct little finger against resistance applied by examiner.



MEDIAN & ULNAR NERVES
Have patient approximate little finger and thumb with hand in prone position.



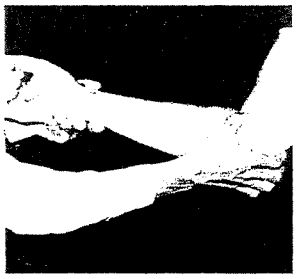
PERONEAL NERVE
Ask the patient to bring foot up. Apply resistance when foot is up. There will be weakness or paralysis when patient is unable to resist the downward movement that is applied to the foot.



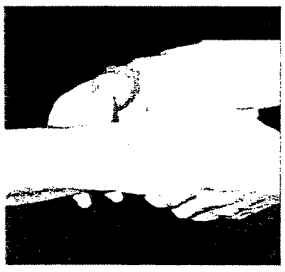
These assessments are to be done with application of resistance by examiner; otherwise early signs of weakness may be missed. A patient with a positive eye exam should be evaluated by an ophthalmologist. Positive hand or foot assessments shall be further evaluated through a hand or foot screen and referred.

PERIPHERAL NERVES

Greater auricular-with the patient's head turned to one side, palpate the nerve as it stretches across the sternomastoid muscle.



Ulnar-palpate above the ulnar groove.



Radial cutaneous-palpate at the lateral border of the radius proximal to the wrist joint.

Posterior tibial-posteriorly and inferiorally to the medial malleolus.

Common peroneal-palpate the popliteal fossa just medial to the biceps femoris tendon, and around the neck of the fibula.

SKIN BIOPSY

A proper site is the single most important factor in the skin biopsy to be evaluated for leprosy. The pathologist will be unable to make a definite diagnosis if bacilli cannot be demonstrated by means of the biopsy. A general rule is that the biopsy should be taken entirely within the lesion, preferably from the active margin if there is one; this is especially important in the non-lepromatous forms of leprosy. There is no necessity to include any normal tissue in the biopsy. When no definite lesion can be found, the site for biopsy should be guided by information from skin scrapings and clinical findings such as decreased sensation and decreased sweating.

The skin biopsy should be made with a biopsy punch or by surgical excision. In all instances, the biopsy should be deep enough to include subcutaneous fat; this depth of biopsy is very important, for often the most prominently involved nerves will be found in the upper portion of the subcutaneous tissue. A 4 mm or larger biopsy punch should be used; a 2 or 3 mm punch biopsy can be made on the face, if necessary. Surgical excision is made 1 cm by 3 mm, with a cold knife; removal of specimens by cautery is to be entirely avoided. A proper fixative should be employed for specimen fixation and transfer; 10% neutral buffered formalin is used routinely. At least five volumes of fixative per volume of tissue should be used.

NERVE BIOPSY

Adequate clinical information should always be submitted with the specimen. The site of the biopsy should always be stated. The attached diagram is helpful. Relevant information includes: number of lesions, changes in sensation, previous diagnosis and present clinical impressions, patient name, date of birth, sex, race, and social security number if available.

For histopathological consultation, at no charge, mail specimens in 10% neutral buffered formalin to:

National Hansen's Disease Programs
Attention: Clinical Laboratory
1770 Physicians Park Drive
Baton Rouge, Louisiana 70816

PROTOCOL FOR SUBMITTING SPECIMENS FOR HISTOLOGICAL EVALUATION OF HANSEN'S DISEASE

National Hansen's Disease Programs
Baton Rouge, Louisiana

The following are the requirements needed before sending a biopsy for routine histological evaluation:

1. A biopsy collected with a 4 – 5 mm punch (2 mm if on face) or surgical excision, which should be deep enough to include subcutaneous fat. This depth is important because often the most prominently involved nerves will be found in the upper portion of the subcutaneous fat. As a general rule, the biopsy should be taken entirely within the lesion, preferably from the active margin if there is one.

2. Place in 10% buffered formalin, at least 5 volumes of fixative per volume of tissue. Label container with patient's name and biopsy site.

3. A brief clinical history including number of lesions, changes in sensation, previous diagnosis and present clinical impressions.

4. The patient's name, sex, race and social security number if available.

5. The patient's date of birth.

6. The submitting doctor's name and the address where the report is to be sent.

7. Send biopsy in leak-proof container.

The following specimens may also be submitted for evaluation (listed in order of preference):

1. Paraffin blocks.

2. Slides of unstained sections - preferably at least 4 slides.

3. Stained slides to include H&E and Fite.

Specimens should be placed in protected mailing containers such as screw-cap cardboard cylinders or padded mailing envelopes to prevent damage.

Specimens are then sent to:

National Hansen's Disease Programs
Clinical Lab
1770 Physicians Park Drive
Baton Rouge, LA 70816
Attn: George Reed or Steve Keas

SKIN SMEARS FOR ACID-FAST BACILLI

PURPOSE:

The skin smear is a valuable, cost-effective tool in the routine management of the Hansen's disease patient. The smear is a means of estimating the number of acid-fast bacteria present, reported as the bacterial index (BI), and is important in determining the type and severity of disease as well as assessing the response to treatment.

GENERAL:

1. Initial skin smears are usually taken from 6 "routine sites" (both earlobes, elbows, and knees) as well as several typical lesions from the patient.

   Repeat smears are obtained from 3 to 4 of the most active sites previously tested to evaluate progress.

2. The time interval between repeat smears is determined by the physician but in general, annual smears are adequate for monitoring response to treatment and during the follow-up period to detect any evidence of relapse.

3. They may be sent in protective mailers to:

   National Hansen's Disease Programs
   Attention: Clinical Laboratory - Skin Smears
   1770 Physicians Park Drive
   Baton Rouge, Louisiana 70816
   Phone: (225) 756-3733

PROCEDURE FOR OBTAINING SMEARS:

1. Universal precautions should be observed in obtaining skin smears.

2. All microscopic slides on which skin smears are made should be precleaned in 70% alcohol, acetone, or alcohol-acetone to remove amorphous debris. The slides are wiped dry with a clean hand towel. Blades that are used in smear taking are likewise cleaned.

3. The skin is cleansed with 70% alcohol and air dried or wiped dry with cotton. (Zepharin tends to make the skin too slippery and is not recommended.)

4. A fold of skin is made relatively avascular by pinching. If the skin cannot be grasped by pinching, it can be compressed. A surgeon's glove may aid in grasping.

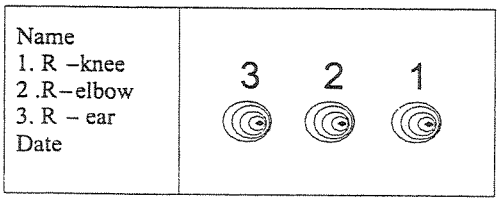
5. Local anesthesia is generally unnecessary. (If there is not adequate decrease in sensation, obtain local anesthesia with 1% Xylocaine, or Ethyl Chloride spray can be carefully applied.) The compression of the skin by pinching aids in the anesthesia.

6. An incision 3-5 mm long and 2-3 mm deep is made with an alcohol-cleansed single-edge razor blade or a scalpel with a #15 Bard-Parker blade may also be used. **The blade or scalpel should be used for only one site and then discarded.** Mild pressure to maintain relative avascularity is continuously applied to the area until an adequate smear has been obtained.

7. A small amount of blood does not interfere with the reading, but large amounts should be avoided and can usually be controlled by the amount of pressure of the pinch. If excessive bleeding occurs, it can be wiped away with a cotton swab.

8. After the incision is made, and before the blade is withdrawn, the inner surface of the wound is scraped with the blade held at a right angle to the incision. Upon scraping, tissue fluid and dermal tissue are obtained.

9. The material is transferred to the cleaned microscope slide. A moderately thick smear, with a visible uniform opacity is made. The smear is made in a circular manner on the slide, **no larger than a pencil eraser (5-7 mm) in diameter**, beginning peripherally and ending in the center, leaving a central "button" (2-4 mm) which can be easily focused upon with the microscope. Slides should be properly labeled as shown in the sample diagram for 3 routine sites.



10. Slides should be air-dried and **NEVER** heat fixed.

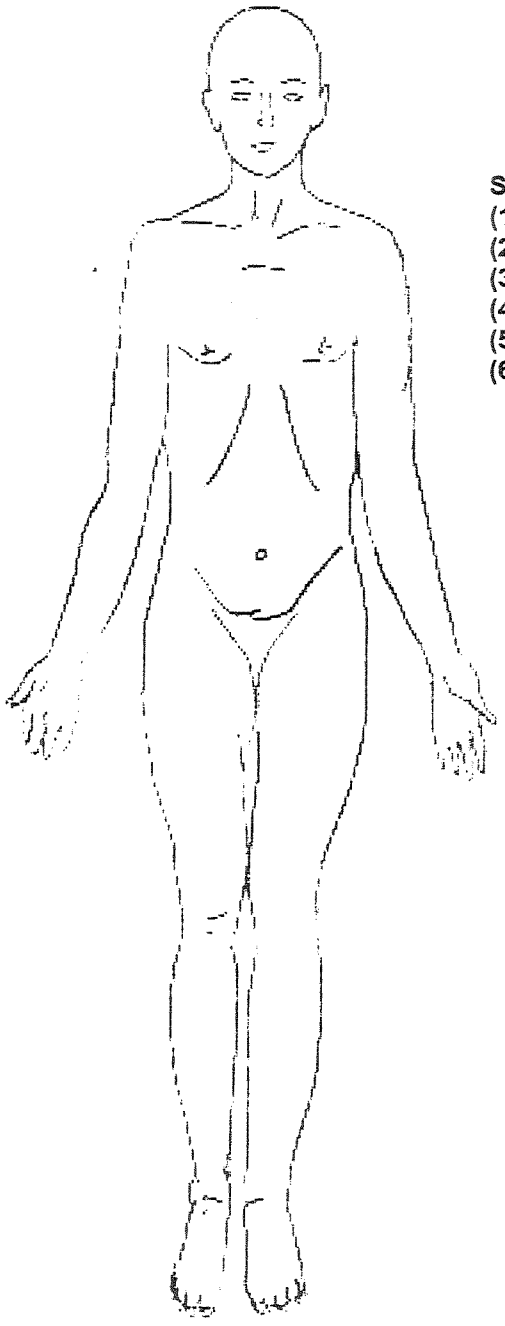
11. A Band Aid is generally sufficient to protect the smear site.

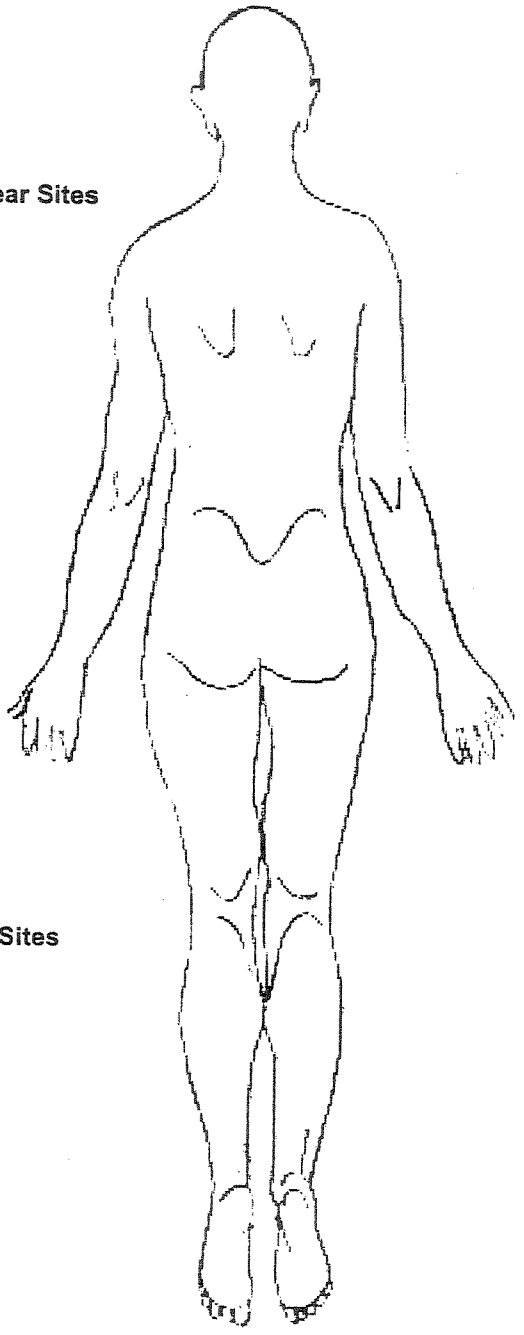
12. A single technician takes all smears to provide for more uniform and consistent results.

13. The smears may be sent to the National Hansen's Disease Programs for reading.

14. A chart to diagram sites of the skin smears or biopsy is attached to "Skin Biopsy" in the appendix. It can be copied for your convenience.

NATIONAL HANSEN'S DISEASE PROGRAMS	SKIN SMEAR / BIOPSY CHART	DATE:
Patient's Name (Last, First, Middle) _____		HD ID No:
Date of Birth: _____	Social Security No. _____	Phone results to:





Skin Smear Sites
(1)-
(2)-
(3)-
(4)-
(5)-
(6)-

Biopsy Sites
(1)-
(2)-
(3)-
(4)-
(5)-
(6)-

Private Physician:
Name: _____
Address: _____
_____

[redacted]

STAINING OF SKIN SMEARS

1. Dry the slide with smear at room temperature. **DO NOT HEAT FIX.**

2. Place slides on a staining rack and flood with 10% formalin for 15 minutes for fixation.

3. Rinse with tap water.

4. Flood slides with Ziehl-Neelsen carbol-fuchsin for twenty minutes. (Always filter stain before each use.)

5. Rinse with tap water.

6. Decolorize with 2% acid alcohol for 1 minute.

7. Rinse slides thoroughly with tap water.

8. Counterstain with alkaline methylene blue for 30 seconds to 1 minute.

9. Rinse with tap water and air dry.

NOTE: Positive and negative control slides must be used each day for quality control purposes.

Z-N Carbol Fuchsin Stain:

Basic fuchsin.....1.0 gm.
Phenol crystals.....5.0 gms.
95% ethanol.....10.0 mls.
Water, to make.....100.0 mls.

Acid alcohol:

Conc. HC1.....2.0 mls.
95% ethanol.....98.0 mls.

Alkaline Methylene Blue:

KOH (10%).....10.0 mls.
Methylene blue..... 0.35 gms.
95% ethanol..... 16.0 mls.
Water to make..... 100.0 mls.

MICROSCOPIC EXAMINATION OF SKIN SMEARS:

The stained smears are examined with a quality microscope using the oil immersion objective (x100) to determine the total number of bacilli. The same individual should read all smears for the purpose of consistency. The smear will have similar numbers of bacilli throughout, however, four separate quadrants of the smear are examined and averaged to establish the Bacterial Index (BI).

REPORTING THE BACTERIAL INDEX (BI):

The results are reported on a 0 to 6+ semi-logarithmic scale using a descriptive phrase or numerical code. This is an indicator of the total bacillary load of the patient. It falls about 1 point per year during effective treatment as dead bacilli undergo lysis and are absorbed.

Very Numerous	(+6)	-	over 1000 bacilli per oil immersion field.
Numerous	(+5)	-	100 to 1000 bacilli per oil immersion field.
Moderate	(+4)	-	10 to 100 bacilli per oil immersion field.
Few	(+3)	-	1 to 10 bacilli per oil immersion field.
Very few	(+2)	-	1 to 10 bacilli per 10 fields.
Rare	(+1)	-	1 to 10 bacilli per 100 fields.
None found	(NF)	-	No AFB seen on entire site.

STANDARDS FOR PERFORMANCE OF HAND SCREEN

The hand screen is intended to record the baseline and risk assessment of patients requiring acute care, or receiving health education, and it helps identify patients in need of treatment to prevent progressive nerve damage (decrease in sensory and muscle function). The majority of patients may not have sensory or muscle involvement of the hands or will have long-standing involvement that is not changing.

Long standing sensory and muscle loss that is unchanging does not need treatment of the nerve, however, the patient may benefit from deformity prevention techniques (splitting/education/adaptive devices).

The sensory testing device used with the Hand Screen is a set of five (5) calibrated nylon filaments mounted on a small rod, which measures levels of coetaneous touch and pressure on a scale of 2.83 to 6.65. The normal threshold level is 2.83.

WHEN TO PERFORM THE SCREEN

- A baseline hand screen is performed on all new patients at the time of diagnosis.
- Annual screens are performed on all patients during chemo therapy for HD:

- Annually until stable for 3 years. Screens shall also be performed as clinically necessary on any patient complaining of muscle weakness, decrease in sensation, or change in function.

PATIENTS WITH NERVE CHANGES:

Patients whose sensory and muscle function has deteriorated over the last 6-12 months are experiencing reaction in the nerves; these are considered "acute" nerves.

Patients with "acute" nerves need immediate attention in order to prevent progression in nerve involvement, and examination by the physician for treatment of the nerve with corticosteroids or other anti-inflammatory agents.

Referral to an occupational therapist may be warranted for patient education in reducing stress on the acute nerve, protection of the nerve, or temporary immobilization.

HAND SCREEN INSTRUCTIONS

PATIENT DATA:

Use middle initial or middle name if available.

Use patient's social security number.

SECTION I SENSORY TEST:

A. Perform the test with the patient's eyes closed or averted.

B. Select the sites to be tested as indicated on the Hand Screen form.

C. Use Filament #1, the lightest, first. If equates to normal sensation (0.05 gram).

D. Apply the filament slowly to bending (just before bending to the heaviest), hold 1.5 seconds, remove slowly.

E. Apply the filament three times (slowly) in succession and record if the patient feels any of the three applications.

F. If the first filament is not felt, proceed to the next heavier filament, repeating the process until a filament is felt.

G. Record the number of the filament first felt in the appropriate blank, next to the appropriate number. If no filament is felt, put a zero in the blank to indicate the test was completed for that site, but the patient did not respond.

H. Do not allow the filament to slide across the skin.

I. Ask the patient to reply "yes" when the filament is felt.

J. Apply the filament along the margin of and NOT on an ulcer site, callous or scar.

SECTION II SKIN INSPECTION:

Use initials indicated on form to mark hand map and for lesions and observations made of the condition of the patient's hands.

SECTION III MUSCLE TESTING:

Results of muscle testing are graded as strong, weak, or paralyzed.

Strong – Normal ROM and full resistance

Weak – Reduced ROM with reduced or not resistance

Paralyzed – No contraction palpable.

1. Abduction of index finger (ulnar).
   Index finger should be abducted with some slight flexion in the knuckle joint, with all other joints straight. Apply resistance at the base of the index finger. Thumb of supporting hand can palpate for possible muscle contraction.

2. Abduction of little finger (ulnar).
   Ask patient to move little finger out and slightly up, palm side up, keeping all the joints of the finger straight. Apply resistance at the base of the little finger. Fingers of your supporting hand will be able to palpate for possible muscle contraction.

3. Abduction of the thumb (median).
   Move thumb away from palm of hand at right angles to the plane of the palm of the hand. Resistance is applied at the base of the thumb, pushing it in to the index finger.

4. Opposition of the thumb (median).
   Have patient make ring with thumb and little finger, try to push thumb out.

5. Wrist extension (radial).
   Ask the patient to make a fist, and try to push the wrist down on the radial side. If weakness is present, patient may not be able to resist or wrist may deviate to unaffected side.

SECTION IV PERIPHERAL NERVE RISK:

Weakness or paralysis is usually not present wherever normal sensation or sweating is found. Loss of sensation and weakness may occur at the same time or sometimes months or years later.

Peripheral nerve involvement of short duration is more apt to be responsive to treatment. Acute nerve involvement may be successfully minimized or reversed by treatment with corticosteroids, anti-inflammatory agents, immobilization,

[redacted]

wrapping to keep it warm, or possibly surgery (nerve transfer).

Classification is graded on a scale of 1 to 4.

Risk Category 1:

A patient in this category may need to be followed for the possibility of further problems.

Risk Category 2:

Tender nerve on stretch or compression, with the ulnar nerve in the area of the olecranon process in the elbow. May be tender on flexion of arm or if pressure applied to area. To palpate for an enlarged nerve, use the four fingers of one hand and gently roll the nerve under them. A normal nerve is slightly thick or may not be palpable at all. A hard, sclerosed nerve is abnormal.

Risk Category 3:

Sensory change in the last 12 months.

Risk Category 4:

Muscle change in the last 12 months.

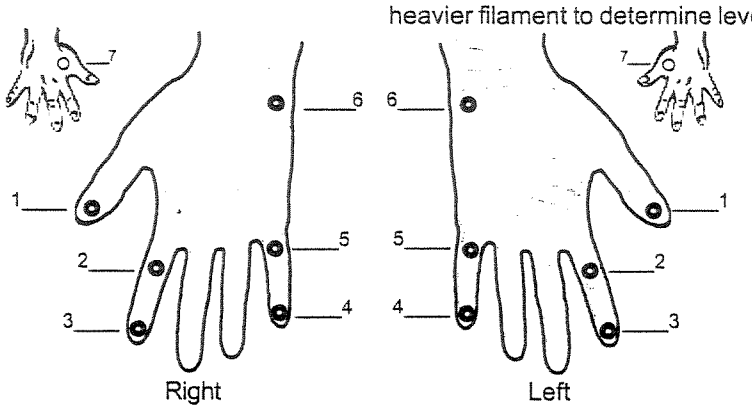
Section V DEFORMITY RISK:

This is classified from a range of 1 to 5, which lists types of disability which may be present in a patient.

Hand Screen forms should be sent to: National Hansen's Disease Programs
1770 Physicians Park Drive
Baton Rouge, LA 70816

PROGRAM NAME:	**HAND SCREEN RECORD**		Date:
Patient's Name *(Last, First, Middle)*:		SS No.	Reaction: Type I ___ Type II ___
Patient's File No.	Medications:	Date of Disease Onset	Classification / Initial __ F/U __

Section I. **SENSORY TESTING:** Use first filament (A) at site indicated *(apply three times)*. If no response, use next heavier filament to determine level of loss.

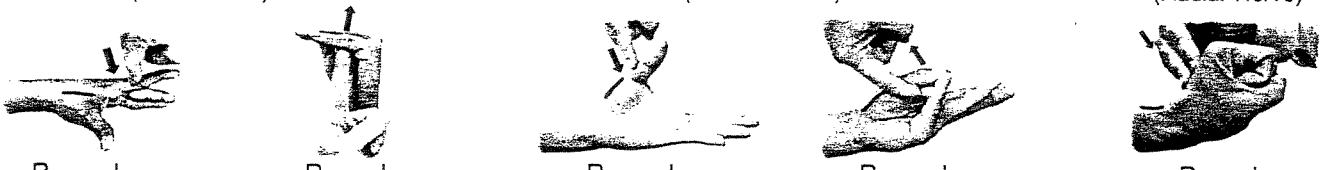


Filament	Force, gms	Interpretation	(Grade Pts.)
A Green (2.83)	0.05	Normal	(5)
B Blue (3.61)	0.20	Residual Texture	(4)
C Purple (4.31)	2.00	Residual Protective Sensation	(3)
D Red (4.56)	4.00	Loss of Protective Sensation	(2)
E Orange (6.65)	300.00	Residual Deep Pressure	(1)

Section II. **SKIN INSPECTION:** Draw and label *(above)*: **W** - Wound, **C** - Callus, **S** - Swelling, **R** - Redness, **D** - Dryness, **T** - Temperature, **M** - Missing, **J** - Contracture, **O** - Other

Section III. **MUSCLE TESTING:** Mark *(below)*: **S** = Strong, **W** = Weak, **P** = Paralysis *(or Grade 5 to 0)*

(Ulnar Nerve) (Median Nerve) (Radial Nerve)



R__ L__ R__ L__ R__ L__ R__ L__ R__ L__

1) Index finger Abduction (FDI)

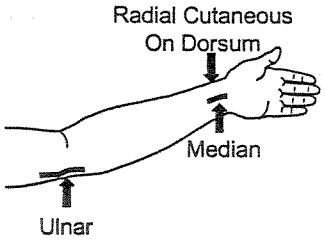
2) Little Finger MP Joint Flex. (L)

3) Thumb Abduction Out of Palm (APB)

4) Thumb to Little Finger (OP)

5) Radial Wrist Extension (ECR)

Section IV. **PERIPHERAL NERVE RISK:** Mark: U, M, R *(or combination)*



1) Enlarged or swollen nerve R ___ L ___
2) Tender / painful on stretch or compression R ___ L ___
3) Sensory change in the last 12 months R ___ L ___
4) Muscle change in the last 12 months R ___ L ___

High Risk *(acute or changing nerve)*: Yes ___ No ___
(refer to physician/therapist)

Section V. **DEFORMITY RISK:** *(Check if present)*

1) Loss of Protective Sensation R ___ L ___
2) Clawed but Mobile Hand R ___ L ___
3) Fingertip Absorption (Mild___ Severe___) R ___ L ___
4) Injuries *(wounds, blisters, etc.)* R ___ L ___
5) Contracted or Stiff Joints R ___ L ___
6) Wrist Drop *(radial nerve)* R ___ L ___

High Risk *(any of the above)*: Yes ___ No ___
(refer for appropriate treatment)

Has there been a change in the hand since any previous exam? Yes __ No __

Examined by:_____

STANDARDS FOR PERFORMANCE OF THE FOOT SCREEN

The initial foot screen is intended to record the baseline status of patient subjective data and clinical signs and symptoms of neurological impairment. The foot screen evaluates history or presence of plantar ulceration, strength of specific muscles, plantar foot sensation, and deformities which can place the foot at risk of injury. After the initial evaluation, screens are performed annually to monitor or pick up any undetected changes by the patient and are indicated more often if the patient perceives any change in sensory, motor or functional status. The screen is a tool to bring up any treatment issues such as wound, callus, and toenail care, footwear and orthotic needs.

The Screen is also used to place the patient in a Risk Category. The foot screen assessment section or risk category serves as a guideline for routine foot checks. This check up is for monitoring and trimming plantar callus and toenails and for checking on appropriateness of patient footwear and orthotics.

The sensory testing device used with the Foot Screen is a nylon filament mounted on a holder and is designed to deliver a 10 gram force when properly applied. Our research has shown that a patient who can feel the 10 gram filament in the selected sites will not develop ulcers.

Routine follow up is based on the objective data and is suggested as follows:

- Category 0 - No Loss of Protective Sensation (LOPS) - annual foot screen only
- Category 1 - LOPS but no deformity - check up every six months
- Category 2 - LOPS and deformity - check up every three months
- Category 3 - LOPS and history of ulceration monthly check ups
- Category 4 - Charcot foot - monthly check ups

WHEN TO PERFORM THE SCREEN

- A baseline foot screen is performed on all new patients at the time of diagnosis.
- Annual foot screens are performed on all patients during chemo therapy for HD and until stable for 3 years.
- Screens shall also be performed as clinically necessary on any patient complaining of muscle weakness, decrease in sensation, or change in function.

FOOT SCREEN ENCOUNTER FORM

Instructions for sensory testing on the foot:

1. Use the 10 gram filament provided to test sensation.
2. Select the sites to be tested based on the Foot Screening Form.
3. Apply the filament perpendicular to the skin's surface. (See diagram A)
4. The approach, skin contact and departure of the filament should be approximately 1 ½ seconds duration.
5. Apply sufficient force to cause the filament to bend (See diagram B)

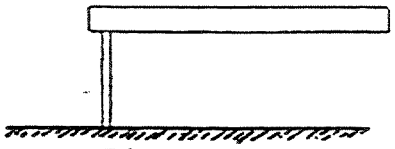


Diagram A

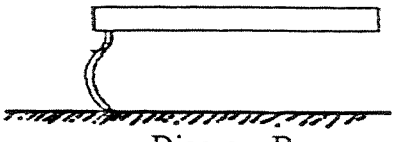


Diagram B

6. Do not allow the filament to slide across the skin or make repetitive contact at the test site.
7. Randomize the selection of test sites and time between successive tests to reduce the potential for patient guessing.
8. Ask the patient to respond "yes" when the filament is felt.
9. Apply the filament along the perimeter of and NOT on an ulcer site, callous, scar or necrotic tissue.
10. Foot screens are performed annually. If the patient has symptoms of neuritis, e.g., burning on the soles of the feet, pain in the lower extremities, or is on treatment for neuritis, the foot screen should be done more frequently to monitor progress or to refer to the clinician.
11. A copy of the Foot Screen must be sent to the NHDP.

HD CLINIC	FOOT SCREEN RECORD		DATE:
PATIENT'S NAME (Last, First, Middle)		SS#	REACTION: TYPE I_____ TYPE II_____
PATIENT'S FILE NO:	MEDICATIONS:	DATE OF HD ONSET:	CLASSIFICATION:
LOWER EXTREMITY SURGERY:		TYPE OF WORK USUALLY DONE:	

Fill in the following blanks with and R, L, or B to indicate positive findings on the right, left or both feet.

Has there been a change in the foot since last evaluation? Yes _____ No _____

Is there a foot ulcer now or history of foot ulcer? Yes _____ No _____

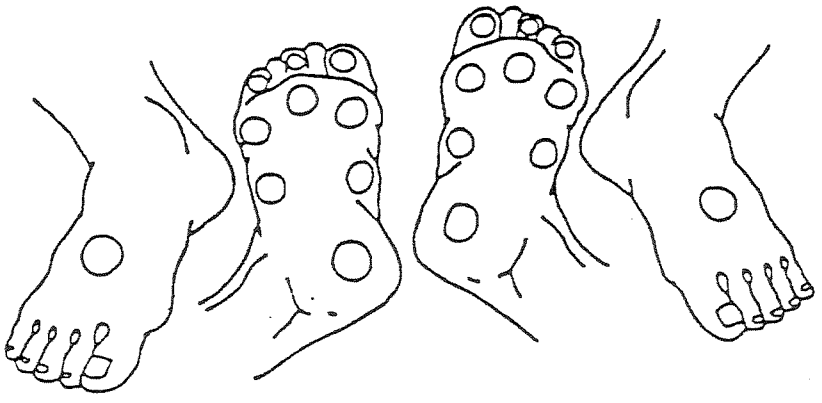
Does the foot have an abnormal shape? Yes _____ No _____

Is there weakness in the ankle or foot? Yes _____ No _____

Are the nails thick, too long or ingrown? Yes _____ No _____

Label: Sensory level with a "+" in the circled areas of the foot if the patient can feel the 10 gram (5.07 Semmes-Weinstein) nylon filament and "-" if he/she can not feel the 10 gram filament.

RIGHT



LEFT

Clinical Appearance Of Skin:

Does the patient use footwear appropriate for his/her category? Yes _____ No _____

RISK CATEGORY:

___ 0 No protective sensory loss

___ 1 Loss of protective sensation (no deformity, or plantar ulcer history).

___ 2 Loss of protective sensation and deformity (no plantar ulcer history).

___ 3 History of plantar ulcer.

PATIENT EDUCATION: Skin care, inspection, footwear

REFERRALS: _____

Date of Next Evaluation:
Category 0 – One Year ____
Category 1 – One Year ____
Category 2 – Six Months ___
Category 3 – One – Three Months ___

WHO GRADING OF DISABILITIES
HANDS AND FEET

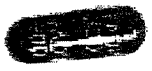
Grade 0: No anesthesia, visible deformity, or damage

Grade 1: Anesthesia present, but no visible deformity or damage

Grade 2: Visible deformity or damage present

Each hand and foot should be assessed and graded separately. "Damage" in this context includes ulceration, shortening, disorganization, stiffness, or loss of part or all of the hand or foot. If any disability found in the patient is due to causes other than leprosy, this fact should be noted.

HANSEN'S DISEASE MEDICATIONS

DRUG NAME	DRUG DOSAGE	HOW TO TAKE **	COMMON SIDE EFFECTS
RIFAMPIN 300 mg 	TAKE AS DIRECTED BY PHYSICIAN **DIRECTIONS:**	TAKE ON AN EMPTY STOMACH 1 HOUR BEFORE MEALS OR 2 HOURS AFTER MEALS NO ANTACIDS *(TUMS, ETC)* WITHIN ONE HOUR OF TAKING	May color urine, sweat, sputum, tears red. May upset stomach or give you flu-like symptoms. Often interferes with other medicine. Inform us if you are taking any new medicines, even birth control pills.
DAPSONE 25 mg  50 mg  100 mg 	TAKE AS DIRECTED BY PHYSICIAN **DIRECTIONS:**	CAN TAKE ON EMPTY OR FULL STOMACH	May cause muscles weakness or give you a sore throat and fever. If this happens, stop the drug and call HD clinic nurse.
CLOFAZIMINE 50 mg 	TAKE AS DIRECTED BY PHYSICIAN **DIRECTIONS:**	TAKE WITH FOOD	May color skin, urine, sweat, sputum or whites of eyes brown. Skin may become dry; use lotion on skin at least twice a day.
PREDNISONE *(drug may vary in colors / sizes)* 5 mg  10 mg  20 mg 	TAKE AS DIRECTED BY PHYSICIAN **DIRECTIONS:**	TAKE WITH FOOD	<u>Drug must be gradually decreased.</u> NEVER ABRUPTLY STOP DRUG! Take as directed by MD. May have increased appetite or increased energy.
OFLOXACIN 200 g 	TAKE AS DIRECTED BY PHYSICIAN **DIRECTIONS:**	TAKE ON AN EMPTY STOMACH ONE HOUR BEFORE MEALS OR TWO HOURS AFTER EATING DO NOT TAKE ANTACIDS OR VITAMINS FOR 2 HOURS BEFORE OR AFTER TAKING MEDICINE	Wear sunscreen in sunlight. Drink juices high in Vitamin C. May cause tenderness in tendons of heel, wrist and shoulder. Call HD clinic nurse to explain these symptoms.
MINOCYCLINE 50 mg  100 mg 	TAKE AS DIRECTED BY PHYSICIAN **DIRECTIONS:**	MAY BE TAKEN ON AN EMPTY OR FULL STOMACH DO NOT TAKE ANTACIDS OR IRON SUPPLEMENTS WHILE TAKING THIS MEDICINE	Wear sunscreen in sunlight. Dizziness can occur. Stop medicine if hives develop. Women can get yeast infections. Call HD nurse if you develop any symptoms of a yeast infection: Vaginal discharge or vaginal itching/burning.

** NOTE: **All medications should be taken with a full glass of water.**

Authorization: Rebecca Finch, RN (Seattle HD Clinic)

NHDP 03/2002
For information: 1-800-642-2477

MEDICINAS PARA LA ENFERMEDAD DE HANSEN

DROGA	DOSIS	COMO SE TOMA **	EFECTOS SECUNDARIOS
RIFAMPIN 300 mg 	TOME COMO INDICADO POR SU MÉDICO **DIRECCIONES:**	TOME EN AYUNAS 1 hora antes de comer o 2 horas despues de comer NO TOME ANTÁCIDOS *(TUMS,etc)* Durante una hora de habérsela tomado	Puede enrojecer la orina, esputo, o lágrimas. Puede irritarle el estómago o causarle síntomas de parecidos a los de la gripa. Puede interferir con otras medicinas. Avísenos si es que está tomando cualquier medicina incluyendo pastillas anticonceptivas. pills.
DAPSONE 25 mg  50 mg  100 mg 	TOME COMO INDICADO POR SU MÉDICO **DIRECCIONES:**	TOME EN AYUNAS O DESPUES DE COMER	Puede provocar debilidad muscular, dolor de garganta y fiebre. En dado caso, descontinue la droga y llame a la enfermera de la clínica HD
CLOFAZIMINE 50 mg 	TOME COMO INDICADO POR SU MÉDICO **DIRECCIONES:**	TOME CON COMIDA	Puede alterar el color de la piel, orina, sudor, y esputo, o la parte blanca de los ojos. Puede resecarle la piel. Use una loción para la piel por lo menos dos veces al dia.
PREDNISONE *(puede variar de color/tarnano)* 5 mg  10 mg  20 mg 	TOME COMO INDICADO POR SU MÉDICO **DIRECCIONES:**	TOME CON COMIDA	<u>Se debe disminuyir gradualmente la dosis de esta droga</u>. NO SE DEBE DETENER BRUSCAMENTEL! Tome como le indique su DOCTOR. Puede aumentar su apetito o energia.
OFLOXACIN 200 g 	TOME COMO INDICADO POR SU MÉDICO **DIRECCIONES:**	TOME EN AYUNAS Una hora antes de comer o Dos horas despues de comer NO TOME ANTÁCIDOS O VITAMINAS DURANTE DOS HORAS ANTES O DESPUES DE HABER TOMADO LA MEDICINA	Aplique bloqueador de sol. Tome jugos con alta concentración de la vitamina "C". Puede causarle dolor en los tendones del talón, muñecas, u hombros. Llame a la enfermera de la clínica HD para explicarle los síntomas.
MINOCYCLINE 50 mg  100 mg 	TOME COMO INDICADO POR SU MÉDICO **DIRECCIONES:**	SE PUEDE TOMAR EN AYUNAS O DESPUES DE COMER NO TOME ANTÁCIDOS NI SUPLEMENTOS DE HIERRO DURANTE DOS HORAS ANTES O DESPUES DE TOMAR ESTA MEDICINA	Aplíquese bloqueador de sol. Puede causar mareos. Detenga la medicina si le salen ronchas. Las mujeres pueden sufrir infecciones de ciertos hongos. Llame a la enfermera de la clínica HD si sufre cualquier síntoma de una infección: flujo vaginal, comezon/ardor.

**** Tome toda medicina con un vaso de agua.****

NHDP 3/2002
Authorization: Rebecca Finch, RN *(Seattle HD Clinic)*
For Information: 1-800-642-2477

CLOFAZIMINE PATIENT ENROLLMENT FORM

(Original to be kept in chart; and COPY faxed or mailed to NHDP)

1. Date of enrollment: _____
2. Patient's full name (Last, First, Middle):_____
3. a) Date of birth: _____ b) Place of birth: _____
4. Race: _____
5. Sex: Male _____ Female _____
6. If female of childbearing age, is pregnancy test negative? Yes___ No___
7. Has patient ever been admitted to NHDP? Yes___ No___ NHDP # (if known):____
8. Date of HD diagnosis: _____
9. Patient's disease classification (circle one):

   a) lepromatous leprosy (LL)
   b) borderline-lepromatous (BL)
   c) borderline (BB)
   d) indeterminate (I)
   e) borderline-tuberculoid (BT)
   f) tuberculoid (TT)

10. Other inclusion diagnoses (circle all that apply):

    a) Known or suspected ENL
    b) Known or suspected dapsone-resistant HD
    c) Relapsed leprosy
    d) Intolerance of other HD medication: _____ (list)
    e) Cranial nerve involvement: _____(list)
    f) Other Nerve involvement: _____ (list)
    g) Prior Clofazimine monotherapy/maintenance therapy

11. Other leprosy related drugs taken during the past year only:

Drug	Date Started	Dose
Dapsone (DDS, Avlosulfone)	_____	_____
Clofazimine (B663, Lamprene)	_____	_____
Rifampin (Rimactane®, Rifadin®)	_____	_____
Others: _____	_____	_____
_____	_____	_____

12. BI on skin scraping or biopsy(s) before start of therapy _____
13. Was written informed consent obtained from this patient? Yes _____ No _____
    Is it available for inspection if required? Yes _____ No _____

Clinical Investigator: _____ (Signature/Date)

[redacted]

CLOFAZIMINE ANNUAL PATIENT REPORT FORM
(Original to be kept in chart; and COPY faxed or mailed to NHDP)

1. Date of report: _____
2. Patient's name (Last, First, Middle): _____
3. Date of birth: _____
4. Patient's disease classification (circle one):

   a) lepromatous leprosy (LL)
   b) borderline-lepromatous (BL)
   c) borderline (BB)
   d) indeterminate (I)
   e) borderline-tuberculoid (BT)
   f) tuberculoid (TT)

5. Other inclusion diagnoses (circle all that STILL apply):

   a) Known or suspected ENL
   b) Known or suspected dapsone-resistant HD
   c) Relapsed leprosy
   d) Intolerance of other HD medication: _____ (list)
   e) Cranial nerve involvement: _____(list)
   f) Other Nerve involvement: _____ (list)
   g) Prior Clofazimine monotherapy/maintenance therapy

6. Other leprosy related drugs taken during the past year only:

Drug	Date Started	Dose
Dapsone (DDS, Avlosulfone)	_____	_____
Clofazimine (B663, Lamprene)	_____	_____
Rifampin (Rimactane®, Rifadin®)	_____	_____
Others: _____	_____	_____
_____	_____	_____

7. BI on skin scraping or biopsy(s) last examination (Date) _____

8. Response to Clofazimine (circle one):

   a) Good, no intolerances
   b) Good, minor hyperpigmentation
   c) Good, tolerable hyperpigmentation
   d) Fair, unacceptable hyperpigmentation
   e) Poor (intolerance of antibiotic)
   f) Unknown
   g) Lost to follow-up

9. Other clofazimine-related problems (circle any appropriate):

   a) Nausea
   b) Bowel motility problems
   c) Dry eyes
   d) Dry skin
   e) Pruritis
   f) Other abnormality: _____ (list)

10. Is patient still on therapy? Yes _____ No _____

(Date Discontinued and Why: _____)

Clinical Investigator: _____ (Signature/Date)

National Hansen's Disease Programs
1770 Physician's Park Drive
Baton Rouge, LA 70816

CONSENT TO PARTICIPATE IN RESEARCH PROTOCOL

Title:
CLOFAZIMINE USE IN THE LONG-TERM TREATMENT OF LEPROSY, PHASE III
(FDA IND # 67,033, Tulane IRB #J0115)

Principal Investigator:
Barbara M. Stryjewska, M.D., 1770 Physician's Park Drive, Baton Rouge, LA 70816, Phone: LA 70816, (225) 756-3712 or (800) 642-2477.

Study Site:
National Hansen's Disease Programs (NHDP) or Authorized Coinvestigator Locations

Sponsor:
National Hansen's Disease Programs, 1770 Physician's Park Drive, Baton Rouge, LA 70816, Phone: LA 70816, (225) 756-3773 or (800) 642-2477.

Purpose:
Clofazimine is a drug, which has been shown by many doctors to be extremely effective in the treatment of leprosy. Due to new limited availability in the United States, the drug is now available only under a research protocol and in that respect is again considered "investigational" despite many years use as a routine antibiotic. Clofazimine is considered to be standard therapy by the National Hansen's Disease Programs and by the World Health Organization, for treatment of multibacillary (many bacteria seen on biopsy) leprosy. Clofazimine may also be given as an alternate or additional drug for use in leprosy with nerve involvement, or in persons with leprosy resistant to other antibiotics. Additionally Clofazimine has activity against ENL (a specific immune reaction with painful skin nodules and fever) seen in multibacillary leprosy.

Potential Risks:
Despite years of experience, Clofazimine is now considered experimental and if I desire to receive the drug I need to be informed of the risks involved. Like any medicine, Clofazimine may occasionally produce undesirable side effects in some people.

1. Changes in skin pigmentation (coloring) may occur in 75-100% of persons taking Clofazimine, beginning over several weeks to months. The color changes can vary greatly so no prediction can be made as to the type of changes any individual patient may experience. Some persons may find their skin appearing only pink to light brown similar to a suntan, while other persons may experience dark brown or bluish coloration. The pigmentation changes intensify as the drug is taken for longer periods or in higher doses, but will decrease and finally vanish once the medication is stopped (however this process also takes many months as well for the change back to be complete).

[redacted]

2. Clofazimine can cause dry and flaking skin in 8-28% of patients, worsening the dry skin problems many leprosy patients already experience due to the infection in their skin. Itching of skin due to dryness may be experienced in 5% of patients.

3. Dryness of the eyes may also be experienced with changes in the color of the white portion of the eyes.

4. Abdominal problems such as nausea may occur in as much as 40-50% of persons taking Clofazimine. Nausea may be lessened by taking the drug with meals. Other but less common gastrointestinal problems also include vomiting, diarrhea, constipation, irregular bowel movements, and even bowel blockage due to ileus (non-movement of intestine). The likely occurrence of abdominal problems also increases with use of Clofazimine at higher doses and for longer periods of time, but will also decrease and resolve once the drug is discontinued. I should report to my doctor at once should I develop new abdominal problem while taking Clofazimine.

5. As with any medicine, unexpected new side effects may appear the longer the drug is used. Thus, regular follow-up appointments with my doctor are essential and I must keep these appointments.

6. This drug, if given to me, is for my use only. I must assume full responsibility to prevent anyone else from taking it.

7. This study does not include the use of Clofazimine for any children or women who may be pregnant, even though the drug could be prescribed to them in the past. If appropriate, I may be asked to obtain a pregnancy test before starting the medicine under this protocol. If I am female and become pregnant while taking the medicine, I must contact my personal physician and Dr. Stryjewska at once to be switched to an alternative medicine for Clofazimine. I will be directed which Hansen's Disease medications I can take safely during pregnancy. This does not apply to men taking the drug whose partners may become pregnant.

Clofazimine may have importance and potential value to myself and others by my taking Clofazimine as an investigational drug. There are risks of undesirable side effects, both known and unknown. The known risks have been explained, but I must recognize that there may be other unknown risks in taking Clofazimine, as there are in taking any drug. Enrollment in this protocol means I accept the risks and desire to take the drug.

Alternative therapies:
Hansen's Disease requires a combination of antibiotics to treat. If I cannot take Clofazimine for any reason, the doctor caring for me will find another combination of antibiotics adequate to treat me after consulting with specialist in Hansen's Disease at NHDP.

Financial Considerations:
In the event of physical injury resulting from taking Clofazimine, full medical treatment is available, but financial compensation for wages lost because of injury or illness is not available. The National Hansen's Disease Programs and the investigators in this protocol will provide necessary medical treatment for any injury or illness that may arise from my participation in this research protocol. However, such medical treatment may be on a fee-for-service basis, payable by myself or by my insurance carrier if covered by them. Full information concerning this can be obtained from the office of the Director, James L. Krahenbuhl, Ph.D., National Hansen's Disease Programs, 1770 Physicians Park Dr., Baton Rouge, LA 70816, (225) 756-3776.

Research Subject's Rights:
The contact person for answers to questions about Clofazimine and my rights, and whom to contact in the event of an injury related to the intake of Clofazimine, is Barbara M. Stryjewska, M.D., Clinical Branch, National Hansen's Disease Programs, 1770 Physicians Park Dr., Baton Rouge, LA 70816, (225) 756-3712 or (800) 642-2477. Additionally I may contact the Tulane University Health Science Center Associate General Counsel, 1430 Tulane Avenue, New Orleans, LA 70112, (504) 988-5031, if I have questions about my rights as a research subject.

Confidentiality and HIPAA Statements:
By enrollment in this protocol I authorize release of my personal information from this study to those agencies designated by the Principle Investigator (Dr. Stryjewska) and/or the granting agency. This information is considered protected health information (PHI) and is individually identifiable, consisting of health and medical information with my personal identification attached, such as medical records, laboratory test results, photographs, and hospital or clinic bills if any. The Federal Privacy Rule requires that I give my authorization before PHI can be disclosed to a third party, such as any study sponsor or use for research. My consent to participate in this research study is separate from consent to allow disclosure and use of PHI. If I agree to participate in this study and authorize the disclosure of my PHI, the information may be reviewed by Dr. Stryjewska and representatives from the Tulane Health Science Center and from the US Food and Drug Administration, to review and copy any of the previously stated medical records. The Privacy rule does not prevent any third party from disclosing my PHI to someone else. My authorization to disclose or use my PHI does not have an expiration date, but I may revoke authorization for the disclosure and use of my PHI at any time.

Offer to answer questions:
I may ask questions now before I enroll in the study, and anytime in the future. My doctor will be happy to answer any questions I have concerning my participation in this protocol. Questions may be directed to Dr. Stryjewska at Clinical Branch, National Hansen's Disease Programs, 1770 Physicians Park Dr., Baton Rouge, LA 70816, (225) 756-3712 or (800) 642-2477; or through any authorized physician coinvestigator.

Summary:
Before giving my consent by signing this form, I have been sufficiently informed of the reason I am being asked to take Clofazimine, the investigational nature of Clofazimine, of the methods, means and duration of administration of the drug, and of the inconveniences, hazards, or adverse effects that may result from my use of this drug.

My taking of Clofazimine is voluntary. I may discontinue taking it whenever I choose and without loss of benefits to which I am otherwise entitled. Such discontinuance will not jeopardize my future treatment but I should inform the doctors if I wish to stop Clofazimine so that an alternative medication can be prescribed in its place. Any questions regarding this study or this form will be answered so that I satisfactorily and completely understand. The individual to contact in this regard is Barbara M. Stryjewska, M.D., Clinical Branch, National Hansen's Disease Programs, 1770 Physicians Park Dr., Baton Rouge, LA 70816, (225) 756-3712 or (800) 642-2477.

If I choose to withdraw from the study, no new information about me will be collected for study purposes unless the information concerns an adverse event (bad effect) related to the study. If such an adverse event occurs, Dr. Stryjewska may need to review and copy my entire medical record. All information already collected for study purposes and any new information about an adverse event will be disclosed to Dr. Stryjewska and to the US Food and Drug Administration. If I decide to withdraw, I should contact Dr. Stryjewska at the above address and telephone number to let her know I am withdrawing from this study.

It is my responsibility to keep appointments with my doctors, to report to them immediately the earliest suggestion of something amiss and to protect others from unauthorized taking of the drug.

I have read this consent form and voluntarily agree to participate in this research study. My signature also authorizes the use and disclosure of the identifiable health information (PHI) as described in this consent form.

_____ _____

Patient/Date Witness/Date

I am unable to read English, but this consent form has been read and explained to me by:

_____ Name of reader

_____ _____

Patient/Date Witness/Date

_____

(Signature of Reader/Date)

Revised NHDP: 01/19/06
IRB Approval: 2/9/06
Sign By: 2/8/07

Patient Initials _____

[redacted]

Programa Nacional de la Enfermedad de Hansen
National Hansen's Disease Program (NHDP)
1770 Physicians Park Drive
Baton Rouge, Louisiana 70816

Consentimiento para Participar en Protocolo de Investigación

Título:
Uso de la Clofazimina en el Tratamiento de la Enfermedad de Hansen, Fase III
(FDA IND #67,033, Tulane IRB #J0115)

Investigador Principal:
Doctora Barbara Stryjewska, Programa Nacional de la Enfermedad de Hansen (NHDP), 1770 Physicians Park Drive, Baton Rouge, Louisiana, 70816, teléfonos (225) 756-3712 o 1-800-642-2477.

Lugar de Investigación:
Programa Nacional de la Enfermedad de Hansen (NHDP) o Localidad de Co-Investigadores Autorizados

Patrocinador:
Doctora Barbara Stryjewska, Programa Nacional de la Enfermedad de Hansen (NHDP), 1770 Physicians Park Drive, Baton Rouge, Louisiana, 70816, teléfonos (225) 756-3701 o 1-800-642-2477.

Propósito:
La Clofazimina es una medicina que ha sido demostrada por muchos médicos de extrema eficacia en el tratamiento de la Enfermedad de Hansen. Debido a su limitada disponibilidad en los Estados Unidos, la medicina solamente está disponible bajo un protocolo de investigación, y por tanto nuevamente se considera "experimental" a pesar de haberse utilizado como antibiótico de rutina por muchos años. La Clofazimina está considerada como terapia establecida por el Programa Nacional de la Enfermedad de Hansen (NHDP) y por la Organización Mundial de la Salud, para el tratamiento del tipo de Hansen multibacilar (gran número de bacterias en una biopsia). La Clofazimina también se puede administrar como medicamento alterno o adicional para uso en personas con la enfermedad de Hansen con envolvimiento neurológico, o en personas con la enfermedad de Hansen resistente a otros antibióticos. Además, la Clofazimina es efectiva contra el Eritema Nodoso Leproso (una reacción específica inmune con nódulos dolorosos en la piel y fiebre) que ocurre en el tipo de Hansen multibacilar.

Riesgos Potenciales
A pesar de los años de experiencia, la Clofazimina se considera ahora experimental y si usted desea ingerir este medicamento necesita estar informado de los riesgos envueltos. Como cualquier medicina, la Clofazimina puede producir efectos secundarios no deseados en algunas personas.

Iniciales de paciente: _____

1. Cambios en la pigmentación (color) de la piel pueden ocurrir en el 75-100% de las personas que ingieren este medicamento, comenzando desde varias semanas a meses después de comenzar el tratamiento. Los cambios en la pigmentación pueden variar grandemente y por ello no se puede predecir el tipo de cambios que pueda experimentar cada paciente individualmente. Algunas personas pueden notar una alteración en el color de la piel de color rosa a color castaño claro parecido a un bronceado solar, mientras otras personas pueden notar una alteración en el color de la piel de castaño oscuro o azulado. Los cambios de pigmentación se intensifican si se ingiere el medicamento por largos períodos de tiempo o en dosis altas, pero disminuye y finalmente desvanece tan pronto deja de ingerir el medicamento (sin embargo este proceso puede tomar muchos meses para que el cambio sea completo).

2. La Clofazimina puede causar piel seca y escamosa en 8-28% de los pacientes, empeorando los problemas de piel seca que los pacientes ya experimentan debido a la infección en la piel. El 5% de los pacientes pueden experimentar picazón en la piel debido a la resequedad.

3. Pueden experimentar sequedad de los ojos y cambios en el color de la parte blanca de los ojos.

4. El 40-50% de las personas que ingieren Clofazimina pueden sufrir problemas abdominales como náusea. La náusea se puede disminuir tomando la medicina con las comidas. Otros problemas gastrointestinales menos comúnes lo son los vómitos, diarreas, estreñimiento, defecación irregular, y obstrucción del intestino por falta de movimiento intestinal. La probabilidad de que ocurran problemas abdominales aumenta con el uso de Clofazimina en dosis altas y por largos períodos de tiempo, pero también disminuyen y desaparecen tan pronto se descontinúa la medicina. Debe notificar inmediatamente a su médico si desarrolla nuevos problemas abdominales mientras ingiere la Clofazimina.

5. Como cualquier medicina, nuevos efectos secundarios pueden aparecer mientras más sea usado el medicamento. Por eso las visitas de seguimiento a su médico con regularidad son esenciales.

6. Esta medicina es recetada sólo para su uso personal y usted asume toda la responsabilidad de evitar que otras personas la ingieran.

7. Esta investigación no incluye el uso de la Clofazimina en niños o mujeres que puedan estar embarazadas, aún cuando hayan ingerido el medicamento anteriormente. Si es recomendable, le pedirán una prueba de embarazo antes de comenzar a ingerir el medicamento mientras esté participando en este protocolo. Si es fémina y resulta embarazada mientras esté ingieriendo el medicamento debe comunicarse inmediatamente con su médico privado y con la doctora Barbara Stryjewska para que le cambien la Clofazimina por otro medicamento alterno.

Iniciales de paciente: _____

Recibirá instrucciones acerca de cuáles medicamentos para la enfermedad de Hansen usted puede ingerir sin riesgos durante su embarazo. Esto no aplica a pacientes masculinos que estén tomando la Clofazimina y sus parejas estén o resulten embarazadas.

Ingerir la Clofazimina experimental puede tener un valor potencial e importante para usted y otras personas. Usted debe entender que hay riesgos de efectos secundarios no deseados, tanto conocidos como desconocidos. Los riesgos conocidos le han sido explicados, pero debe entender que pueden haber otros riesgos desconocidos al tomar este medicamento. Su participación en este protocolo significa que usted acepta los riesgos y desea tomar el medicamento.

Alternativas de Tratamientos
La enfermedad de Hansen requiere una combinación de antibióticos para el tratamiento. Si usted no puede ingerir la Clofazimina por cualquier razón, su médico le recomendará otra combinación de antibióticos adecuada para su tratamiento luego de consultar con un especialista de la enfermedad de Hansen en el Programa Nacional de la Enfermedad de Hansen (NHDP).

Consideraciones Financieras
En el evento de daño físico que resulte por ingerir la Clofazimina, recibirá tratamiento médico completo, pero no recibirá compensación financiera por pérdida de sueldo por consecuencia de daño físico o enfermedad. Puede obtener información completa relacionada a este tratamiento a través de la oficina del Director, James L. Krahenbuhl, Ph.D., del Programa Nacional de la Enfermedad de Hansen (NHDP), 1770 Physicians Park Drive, Baton Rouge, Louisiana., 70816, teléfonos (225) 756-3776, o al 1-800-642-2477. Para obtener respuestas a preguntas o preocupaciones relacionadas a este tratamiento y sus derechos, y en caso de daño causado por la Clofazimina, se puede comunicar con la doctora Barbara Stryjewska, Rama Clínica, Programa Nacional de la Enfermedad de Hansen (NHDP), 1770 Physicians Park Drive, Baton Rouge, Louisiana, 70816, teléfonos (225) 756-3712, o al 1-800-642-2477. Los investigadores de este protocolo y el Programa Nacional de la Enfermedad de Hansen (NHDP) le brindaran tratamiento médico para cualquier daño o enfermedad que pueda surgir de su participación en este Protocolo de Investigación. Sin embargo, dicho tratamiento médico será ofrecido en base a honorarios pagados por usted o con cargos a su cubierta de seguro médico.

Confidencialidad e Informes de la Ley Federal HIPAA (Acta de Protección de Información de Salud Personal)
Al participar en este protocolo usted autoriza a divulgar información personal (PHI) de este estudio a aquellas agencias designadas por el investigador principal (doctora Stryjewska) y/o la agencia otorgante. Esta información está considerada información de salud confidencial (PHI) e identificada individualmente, constando de información personal médica y de salud con su identificación personal adherida, incluyendo expedientes médicos, resultados de exámenes de laboratorio, fotografías, y facturas de hospital o clínicas, si alguna. La Ley Federal de Confidencialidad (HIPAA) requiere que

usted autorize la divulgación de su información confidencial (PHI) a otras agencias o para otros estudios investigativos. Su consentimiento para participar en este estudio investigativo está separado de su autorización para la divulgación de su información confidencial (PHI) y de salud. Si usted acepta participar en este estudio investigativo y autoriza a que se divulgue su información confidencial (PHI) y de salud, esta información puede ser revisada por la doctora Stryjewska (como Patrocinadora de este estudio investigativo) y representantes del Centro de Salud y Ciencias Tulane y de la Administración de Drogas y Alimentos de Estados Unidos, y reproducir y copiar cualquier documento médico antes mencionado. La Ley Federal de Confidencialidad (HIPAA) no impide que estas agencias aquí nombradas puedan distribuir dicha información (PHI) a otras agencias. Su autorización para divulgar o usar su información confidencial y de salud (PHI) no tiene fecha de expiración, pero usted puede revocar esta autorización para la divulgación o uso de esta información en cualquier momento.

Respuestas a Sus Preguntas
Usted puede hacer preguntas antes de participar en esta estudio investigativo, y en cualquier momento durante la duración de dicho estudio. Su médico está en la mejor disposición de brindarle respuestas a cualquier pregunta que usted tenga relacionada a su participación en este protocolo. Para más información al respecto, se puede comunicar con la doctora Barbara Stryjewska, Rama Clínica, Programa Nacional de la Enfermedad de Hansen (NHDP), 1770 Physicians Park Drive, Baton Rouge, Louisiana, 70816, teléfonos (225) 756-3712 o al 1-800-642-2477, o a través de cualquier médico co-investigador autorizado.

Resumen
Antes de firmar esta forma de consentimiento para participar en esta investigación, a usted se le ha brindado información adecuada sobre la razón para recomendar la Clofazimina, su naturaleza experimental, los métodos, modos y duración de la administración del medicamento, y de los inconvenientes, riesgos, o efectos adversos que pueden resultar al ingerir este medicamento.

El uso de la Clofazimina es voluntario. Usted puede descontinuar el tratamiento en cualquier momento sin pérdida de beneficios a los cuales tiene derecho. Su tratamiento no se verá afectado en el futuro, pero debe informar a su médico si desea descontinuar la Clofazimina para que se le pueda recetar una medicina alterna. Si tiene preguntas relacionadas a este estudio investigativo o a esta forma de consentimiento, le serán contestadas de manera satisfactoria. Se puede comunicar con la doctora Barbara Stryjewska, Rama Clínica, Programa Nacional de la Enfermedad de Hansen (NHDP), 1770 Physicians Park Drive, Baton Rouge, LA, 70816, teléfonos (225) 756-3712 o 1-800-642-2477.

Si usted decide descontinuar su participación de este estudio, no se recopilará información personal para propósitos investigativos a menos que dicha información esté relacionada con algún efecto adverso relacionado al estudio. Si tal efecto adverso ocurre, la doctora Stryjewska tendrá que revisar y copiar su expediente médico completo. Toda información ya recopilada para propósitos investigativos y alguna información nueva

Iniciales de paciente: _____

basada en algún efecto adverso será suministrada a la doctora Stryjewska y a la Administración de Drogas y Alimentos de Estados Unidos. Si usted decide no participar en este estudio investigativo, debe comunicarse con la doctora Stryjewska a la dirección y número telefónico arriba indicado para notificarle su decisión.

Es su responsabilidad mantener todas las citas con sus médicos, de notificarles inmediatamente cualquier malestar, y de prevenir el uso de esta medicina por otras personas que no estén autorizadas a ingerir la misma.

He leído esta forma de consentimiento y voluntariamente acepto participar en esta investigación. Mi firma también autoriza el uso y divulgación de mi información confidencial y de salud (PHI) según explicado en esta forma de consentimiento.

Esta forma de consentimiento está vigente de 09 de Febrero 2006 a 08 de Febrero 2007.

_____ _____

Paciente/Fecha Testigo/Fecha

Yo no puedo leer, pero esta forma de consentimiento se me ha leído y explicado y entiendo su contenido.

_____ Nombre del(la) Lector(ra)

_____ _____

Paciente/Fecha Testigo/Fecha

_____

Firma del(la) Lector(ra)

Revisado NHDP: 01/19/06
Aprobado por IRB: 02/09/06
Firmar antes de: 02/08/07

Iniciales de paciente: _____

Instructions for Completing the Hansen's Disease *(Leprosy)* Surveillance Form

The Hansen's Disease or Leprosy Surveillance Form *(LSF)* is the document used to report leprosy cases to the U.S. National Hansen's Disease Registry. These data are used for epidemiological, clinical, and basic research studies throughout the National Hansen's Disease Program *(NHDP)*, and are the official source for information on leprosy cases in the U.S.

The information requested on the LSF is used by many clinicians and researchers, and collection of all information is highly desirable. However, the fields that are **boldfaced** on the form and in the instructions below are considered to be the minimal information needed to register a patient. Failure to provide this information will result in the form being returned which creates additional work and may cause delays in obtaining program services for the patient.

1. **Reporting State:** Use the abbreviation of the state from which the report is being sent. This is usually the state of the clinician's office and not necessarily the patient's resident state.
2. **Date of Report:** This is date of the initial LSF completion. If patient was previously reported and has relapsed, write the word "RELAPSE" next to the date.
3. Social Security Number: self-explanatory.
4. **Patient Name:** Self-explanatory.
5. **Present Address:** Please include the county and zip code which are used to geographically cluster patients.
6. **Place of Birth:** Include state and county, if born in the U.S., or the country, if foreign born.
7. **Date of Birth/Sex:** Self-explanatory.
8. **Race/Ethnicity:** This information should be voluntarily provided by the patient. If the patient refuses or indicates a race/ethnicity category not listed, check the "Not Specified" box.
9. **Date Entered the U.S.:** For patients who have immigrated to the U.S., provide the month and year of entry.
10. Date of Onset of Symptoms: This information is usually the patient's recollection of when classic leprosy symptoms *(rash, nodule formation, parenthesis, decreased peripheral sensation, etc.)* were first noticed.
11. **Date Leprosy First Diagnosed:** Provide the month and year a diagnosis was made. This usually coincides with a biopsy date if one was performed.
12. **Type of Leprosy:** Classify the diagnosis based on one of the ICD-9-CM diagnosis codes.
    030.0 Lepromatous Leprosy *(macular, diffuse, infiltrated, nodular, neuritic – includes Ridley-Jopling [RJ], Lepromotous [LL] and Borderline lepromatous [BL])*: A form marked by erythematous macules, generalized papular and nodular lesions, and variously by upper respiratory infiltration, nodules on conjunctiva or sclera, and motor loss.
    030.1 Tuberculoid Leprosy *(macular, maculoanesthetic, major, minor, neuritic – includes RJ Tuberculoid [TT] and Borderline tuberculoid [BT])*: A form marked by usually one lesion with well-defined margins with scaly surface and local tender cutaneous or peripheral nerves.
    030.2 Indeterminate *(uncharacteristic, macular, neuritic)*: A form marked by one or more macular lesions, which may have slight erythema.
    030.3 Borderline *(dimorphous, infiltrated, neuritic – includes RJ Borderline [BB] or true mid disease only)*: A form marked by early nerve involvement and lesions of varying stages.
    030.8 Other Specified Leprosy: Use this code when the diagnosis is specified as a "leprosy" but is not listed above *(030.0-030.3)*.
    030.9 Leprosy, Unspecified: Use this code when the diagnosis is identified as a "leprosy" but is not specified as to type.
13. Diagnosis of Disease: Enter INITIAL biopsy and skin smear dates and results.
14. **Residence *(Pre-diagnosis)*:** List all cities, counties, and states in the U.S. and all foreign countries a patient resided in BEFORE leprosy was diagnosed. This information is used to map all places where U.S. leprosy cases have resided.
15. Disability: Indicate any sensory abnormalities or deformities of the hands and feet or lagophthalmos of the eyes.
16. Current Household Contacts: Self-explanatory.
17. Current Treatment for Leprosy: Indicate all drugs used for initial treatment.
18. **Name and Address of Physician or Investigator:** Self-explanatory.

HANSEN'S DISEASE *(LEPROSY)* SURVEILLANCE FORM

NATIONAL HANSEN'S DISEASE PROGRAMS
1770 PHYSICIANS PARK DRIVE
BATON ROUGE, LA 70816
1-800-642-2477

1 Reporting State ☐☐

2 Date of Report Mo. ☐☐ Day ☐☐ Yr. ☐☐

3 Social Security Number ____/____/____

4 Patient Name: *(Last)* *(First)* *(Middle)*

5 Present Address: Street _____ City _____

County _____ State _____ Zip _____

6 Place of Birth:

State _____ County _____

Country _____

7 Date of Birth: Mo. ☐☐ Day ☐☐ Yr. ☐☐

Sex: ☐ Male ☐ Female

8 Race/Ethnicity: ☐ White, Not Hispanic ☐ White, Hispanic ☐ American Indian, Alaska Native ☐ Indian, Middle Easterner ☐ Black, Not Hispanic ☐ Black, Hispanic ☐ Asian, Pacific Islander ☐ Not Specified

9 Date Entered U.S. Mo. ☐☐ Yr. ☐☐

10 Date of Onset of Symptoms: Mo. ☐☐ Yr. ☐☐

11 Date Leprosy First Diagnosed: Mo. ☐☐ Yr. ☐☐

12 Type of Leprosy: *(ICD – 9- CM Code)*

☐ Lepromatous *(030.0 – LL, BL)* ☐ Indeterminate *(030.2 - IN)* ☐ Other Specified Leprosy *(030.8)*

☐ Tuberculoid *(030.1 – TT, BT)* ☐ Borderline *(030.3 - BB)* ☐ Leprosy, Unspecified *(030.9)*

13 Diagnosis of Disease:

Was Biopsy Performed? ☐ Yes ☐ No

Date ____/____/____

Result _____

Skin Smear ☐ Yes ☐ No

Date ____/____/____

BI: Positive _____ Negative _____

15 Disability:

	Hands Yes / No	Feet Yes / No	Eye
Sensory Loss	☐ ☐	☐ ☐	Lagophthalmos?
Deformity	☐ ☐	☐ ☐	Yes ☐ No ☐

14 List all places in the U.S.A. and all foreign countries a PATIENT resided *(Including Military Service)* BEFORE leprosy was diagnosed.

TOWN	COUNTY	STATE	COUNTRY	INCLUSIVE DATES From Mo./Yr.	INCLUSIVE DATES To Mo./Yr.

16 Current Household Contacts

Name/Relationship

1 _____

2 _____

3 _____

4 _____

5 _____

17 Current Treatment for Leprosy: *(check all that apply)*

☐ Dapsone

☐ Rifampin

☐ Clofazimine

☐ Other *(list)* _____

18 Name and Address of Physician: _____

Investigator:

This form may be FAXED to NHDP at (225) 756-3706

DHNDP-3/2003

ATTACHMENT C

Health Resources and Services Administration
Contractor Past Performance Evaluation

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1. FINAL REPORT _____ INTERIM REPORT _____ *(Check one)*

2. REPORTING PERIOD: *(From)* *(To)*

3. CONTRACTING OFFICER:

4. CONTRACT NUMBER:

5. CONTRACTOR NAME:
DEPARTMENT/ COMPONENT:
ADDRESS:
CITY: STATE: ZIP CODE:

6. CONTRACT AWARD DATE:
CONTRACT EXPIRATION DATE:

7. CONTRACT VALUE : $

8. DESCRIPTION OF REQUIREMENT *(Title)* :

---

9. RATINGS

Circle the number that corresponds to the rating for each category *(see attached Rating Guidelines)*, and provide comments to support the rating.

QUALITY OF PRODUCT OR SERVICE Rating 0 1 2 3 4 5
Comments:

COST CONTROL[1] Rating 0 1 2 3 4 5
Comments:

[1] Not applicable to fixed-price type contracts

Health Resources and Services Administration
Contractor Past Performance Evaluation

TIMELINESS OF PERFORMANCE Rating 0 1 2 3 4 5
Comments:

BUSINESS RELATIONS Rating 0 1 2 3 4 5
Comments:

10. SUBCONTRACTS

Are subcontracts involved? Yes No *(Circle one)*
Comments: [Briefly summarize the quality of performance of major subcontractors. This information serves two purposes: (1) it provides some insight into the contractor's effectiveness in managing its subcontractors; and (2) it provides information that may be useful for future procurements when evaluating the past performance of offerors that have only performed as subcontractors.]

11. KEY PERSONNEL

PROJECT MANAGER/PRINCIPAL INVESTIGATOR *(name)* :
Comments:

KEY PERSON *(name)* :
Comments:

KEY PERSON *(name)* :
Comments:

12. CUSTOMER SATISFACTION

Is/was the contractor committed to customer satisfaction?
Yes No *(Circle one)*

Would you recommend selection of this firm again?
Yes No *(Circle one)*

13. PROJECT OFFICER (name) :
SIGNATURE: _____ Date_____
Phone: FAX:
Internet Address:

14. CONTRACTING OFFICER CONCURRENCE: *(Initial)* _____
Date:

15. CONTRACTOR'S REVIEW:
Were comments or additional information provided?
Yes No *(Circle one)*

If yes, they are:

On file in:

_____ _____
(Location) *(Phone)*
Attached: _____ *(Check if attached)*

CONTRACTOR'S REPRESENTATIVE: *(name)*

[redacted]

SIGNATURE: _____ Date_____
Phone: FAX:
Internet Address:

16. AGENCY REVIEW:

Were contractor comments reviewed at a level above the contracting officer?
Yes No *(Circle one)*

If yes, Agency Decision is:
On file in:

_____ _____
(Location) *(Phone)*
Attached: _____ *(Check if attached)*

17. SUMMARY RATINGS:

QUALITY: _____ COST CONTROL: _____

TIMELINESS OF
PERFORMANCE: _____ BUSINESS RELATIONS: _____

18. CONTRACTING OFFICER *(name)* :

SIGNATURE: _____ Date_____
Phone: FAX:
Internet Address:

ATTACHMENT D – BILLING INSTRUCTIONS

INVOICE INSTRUCTIONS FOR FIXED-PRICE CONTRACTS

General The Contractor shall submit vouchers or invoices as prescribed herein.

Format Standard Form 1034, Public Voucher for Purchases and Services Other Than Personal, and Standard Form 1035, Public Voucher for Purchases and Services Other Than Personal--Continuation Sheet, or the payee's letterhead or self-designed form should be used to submit claims for reimbursement.

Number of Copies As indicated in the Invoice Submission clause in the contract (Section G).

Frequency Invoices submitted in accordance with the payment clause shall be submitted upon delivery of goods or services unless otherwise authorized by the contracting officer. Invoices may be submitted in accordance with the contract payment schedule but no more frequently then monthly. The Government will consider payments made against any of these invoices as Partial Payments.

Preparation and Itemization of the Invoice The invoice shall be prepared in ink or typewriter as follows:

(a) Paying office and address

(b) Invoice Number

(c) Date of Invoice

(d) Contract number and date

(e) Payee's name and address. Show the contractor's name (as it appears in the contract), correct address, and the title and phone number of the responsible official to whom payment is to be sent. When an approved assignment has been made by the contractor, or a different payee has been designated, then insert the name and address of the payee instead of the contractor.

(f) Description of goods or services, quantity, unit price (where appropriate), and total amount.

Currency All HRSA contracts are expressed in United States dollars. Where expenditures are made in a currency other than United States dollars, billings on the contract shall be expressed, and reimbursement by the United States Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency

fluctuations may not be a basis of gain or loss to the contractor. Notwithstanding the above, the total of all invoices paid under this contract may not exceed the United States dollars authorized.